

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

October 9, 2024

Richmond, Virginia

Scott Biggins, MD, Chair

Shimul Shah, MD, MHCM, Vice Chair

Introduction

The Committee met in Richmond, Virginia on 10/09/2024 to discuss the following agenda items:

1. Health Resources and Services Administration (HRSA) Contract Award Q and A: TBD
2. Continuous Distribution: Public Comment Review
3. Continuous Distribution: Split Liver
4. Continuous Distribution: Travel Efficiency
5. Working Lunch: NLRB Project Update
6. Non-Standard and Standard Score Recommendation Data Requests
7. Update: Hepatocellular Carcinoma (HCC) Stratification Subcommittee
8. OPTN Multi-organ Transplantation Committee Update
9. Continuous Distribution: Exceptions & Median Meld at Transplant (MMaT)
10. Open Forum

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

1. HRSA Contract Award Q and A: TBD

Presentation Summary

HRSA will update the Organ Procurement and Transplantation Network (OPTN) committees by the end of October on how recent contract changes will impact their day-to-day activities. HRSA will also use committee questions to create content for communication to all committees and this may take place in the form of a town hall.

Summary of Discussion:

No decisions were made regarding this agenda item.

One member voiced support for UNOS staff members and expressed a concern that with the new contract system a lot of organ transplant expertise would be lost without UNOS. The chair seconded this notion and expressed an interest in what the structure would be under the new contract system and what that would mean for the OPTN committees.

Next steps:

There are no next steps for this agenda item.

2. Continuous Distribution: Public Comment Review

Presentation Summary

The Continuous Distribution of Livers & Intestines Update of Summer 2024 received 55 total public comments with the most comments coming from Pennsylvania and California. Of the 55 public comments, 25 of them came from transplant hospitals. The Committee sought feedback for their work on continuous distribution (CD), specifically asking for input on travel efficiency, body surface area (BSA), normothermic regional perfusion (NRP) and normothermic machine perfusion (NMP), HCC stratification, and pediatric candidates.

Common themes for Travel Efficiency included:

- A threshold of between 90 minutes and 2 hours before a center decided to fly an organ over driving it.
- A suggested 120 miles threshold for drive vs fly
- Urban areas may have traffic considerations that alter decisions to fly or drive.
- That the medical urgency of a case should outweigh proximity
- That cold ischemia time (CIT) and overall travel time including potential delays are more critical considerations.

Common themes for Body Surface Area included:

- Adding a donor modifier for BSA will help identify livers that may be more appropriately sized for small-statured candidates.
- Additional donor factors could include high Body Mass Index (BMI), donor instability (high pressor requirements) prolonged donor hospitalization, significantly elevated donor liver enzymes, intraoperative reallocations, and decreasing the donor age limit to 65.
- Additional priority is needed for candidates with low BSA.
- Before any changes to BSA, the Committee should analyze the impact and any interaction of adding BSA adjustment to Model for End-Stage Liver Disease (MELD) 3.0

Common themes for Emerging Technologies included:

- The increased use of NRP and NMP may change what organs are considered medically complex.
- That it will be difficult to set rating scales as emerging technologies are rapidly changing the landscape, and any rating scale needs to be easy to adjust to accommodate this fact.
- The rise of these technologies has significantly increased the cost of liver transplants.

Common themes for Hepatocellular Carcinoma (HCC) Stratification included:

- Stratification of HCC patients should be based on tumor size with an increased prioritization of HCC patients with prolonged waiting times (e.g., greater than one year)
- HCC patients should not be prioritized over patients with a lab MELD over 28
- HCC stratification should split patients into low risk and high-risk categories.

Common themes for Pediatric Candidates included:

- Match runs need to have a system that ensures children are highly prioritized for pediatric organs.
- It is important to track the transplant of pediatric donors into pediatric recipients.

- The Committee should consider a more meaningful variable than “willingness to accept a split liver.”
- The Committee should validate the Pediatric Optimizing Prediction of Mortality (OPOM) model compared to Pediatric End-Stage Liver Disease (PELD) to ensure there are no unexpected disadvantages to its use.

Summary of Discussion:

Decision #1: The Committee decided to place a data request for information regarding what percentage of listed patients are set at the floor of 40 lbs. versus any other listing.

The Vice chair said the Committee needed to consider if travel efficiency was an important metric outside of cost now that machine perfusion has altered how long organs remain viable. They noted in some cases their center was choosing to drive organs even longer distances because it was less costly, and perfusion kept the organs viable longer. There was some consensus that whatever the Committee chooses to do, they would need to make sure it was adjustable as current technology changed.

There was some discussion over the interaction between BSA and MELD 3.0 and the effects this would have on small patients. The Committee felt it could be examined further but that what they had done so far showed MELD 3.0 would work well for smaller patients.

On the topic of emerging technologies, there was some discussion about what constitutes a medically complex case. Donation after Circulatory Death (DCD) organs are far more viable than they use to be due to NRP and NMP. DCD organs are being used more frequently and the outcomes are positive, so more transplant programs are willing to use them. However, they are still hard for organ procurement organizations (OPOs) to place logistically as the ability to use NRP and NMP is not evenly distributed across the country and some transplant centers are still reluctant to use DCDs. The Committee acknowledged that the definition of medically complex organs may need to change in the future and that it should be easier to do so under continuous distribution.

The Committee voiced a concern that data is needed on the use of NRP and NMP to make informed decisions. There is currently a workgroup attempting to overcome the difficulties of collecting data on NRP and NMP. Some difficulties include coordinating data collection from all the different stakeholders and ensuring patient data is protected from third party access. Some data on NRP and NMP use is set to be collected upon Office of Management and Budget (OMB) approval. The Committee wanted to go on record saying the rapid collection of NRP and NMP data is of critical importance.

One member asked if the Committee received any input on HCC priority points and if they should award priority points instead of the patient’s lab MELD or if they should award points on top of the patient’s lab MELD. The Chair said they did not receive any feedback on that, and that the question will need to be discussed by the HCC Subcommittee.

One member reported feedback that practitioners were concerned pediatric patients are not getting properly prioritized under the current system because around 40-50% are getting PELD model exception points. Some transplant centers are overcoming this by relying on living donors but not every center has that capability.

There was also some discussion of how to use split livers to get more pediatric patients transplanted. Currently this involves asking a patient who received an offer for a liver if they would be willing to split the liver once they received an offer. One member asked if there was a way to split the liver ahead of time and then award patients willing to accept a split liver more priority points to generate more split

livers and the ability to transplant more pediatric patients. Another member commented that unfortunately split livers do not always make it to pediatric patients so split livers will not solve the issue alone. The Committee discussed giving priority to patients at transplant centers that specialize/have a history in doing split liver transplants. The Committee expressed concern about awarding points to patients in specific centers as not everyone would have access to those centers.

The Committee discussed problems with the current categorical system of allocation and how adults may end up being prioritized over children in that system. They discussed adding priority points to pediatric patients but agreed that as the number of pediatric patients fell the priority points would have to be adjusted. The Committee agreed that most of these issues should be alleviated by switching to continuous distribution. They also agreed that even though it would not solve all the issues, the continuous distribution system is more adaptable, enabling the Committee to make future changes more easily to further correct pediatric priority. The Committee expressed that it is their goal to eliminate wait time for pediatric patients once they are listed for transplant.

The Committee also discussed if the waitlist-liver donor acceptance criteria threshold of 40 lbs. should be adjusted. The question was prompted by two transplant centers recently requesting a change in this filter. The Committee stated this filter was likely in place to prevent adult patients from getting very small livers better suited to pediatric patients. The Committee acknowledged that removing this filter would not change the match list with pediatric patients still being listed before adult patients. The Committee felt this filter which was passed in 1996 was a bit outdated and an example of a hard boundary that the continuous distribution system is being designed to overcome. The Vice Chair asked if the Committee had any justification for not removing this boundary. The Committee decided it wanted more data on this situation before making a final decision.

Next steps:

The Committee will wait for the data request on the 40 lbs. threshold and let the pediatric community know once the Committee has made their decision on this item.

3. Continuous Distribution: Split Liver

Presentation Summary

The Liver Committee has identified ten, eleven if HCC stratification is included, attributes that meet at least one of the four goals for Liver Continuous Distribution. These goals and attributes are as follows:

Medical Urgency – Prioritize those with high mortality on the waitlist.

- Medical Urgency Score
- Liver-intestine Registration

Biological Disadvantages – Increase graft and recipient post-transplant survival/longevity matching.

- Candidate Blood Type
- Body Surface Area (BSA)

Patient Access – Increase transplant opportunities for candidates who are medically harder to match.

- Pediatric Priority
- Liver-intestine registration
- Prior Living Donor
- Split Liver Transplant

- Geographic Equity

Placement Efficiency – Consider resource requirements needed to match, transport, and transplant an organ.

- Travel Efficiency
- Utilization Efficiency

Split liver utilization within continuous distribution can help to eliminate pediatric waitlist mortality and address donor-recipient size matching for small candidates. Current issues to address include how to ensure that centers that indicate split livers usage have the capability to do it and how to streamline split liver offers since there is variability on how OPOs offer split livers.

Split liver utilization is currently underutilized, in part because prior to the donor risk index (DRI) model, split liver transplantation had a high hazard ratio which has led to a negative bias against the practice. Now the outcomes for split liver transplants (SLT) are similar to the outcomes of full graph liver transplants. Many centers mark patients eligible for SLT but do not perform them. The majority of SLTs are performed by ten transplant centers and their rate of discard for either segment of the liver is much lower than other centers.

In practice when livers are split the left lateral segments are used for children and right tri section graph is used for adults. The primary center has full control over how livers are split, often they take things like the celiac, the portal vein, the inferior vena cava, and the bile duct which results in the right segment of the liver being far less useful which increases the rate at which they are discarded.

Current OPTN policy states that the OPO must offer the second segment according to the match run but if the segment has not been allocated by the time the deceased donor organ procurement has started the transplant hospital must offer it to a candidate registered with the transplant program, or any medically appropriate candidate on the list. This policy means that there often is not enough time to place the second segment of liver which results in a lot of right-side liver graphs not being used.

Region 8 tried a different variance of policy where the transplant program deciding to do a split must notify the OPO so they can offer the remaining segment following the same match run used to allocate the liver. The data showed this variance led to a decrease in split liver transplants after the implementation of this variance, but it should be noted the Covid-19 pandemic occurred during this time.

Additional considerations for the Committee include:

- How to include donor-based incentives for SLT in CD
- How to preserve pediatric access through SLT
- How to address the low number of centers specializing in SLT
- If it is possible to pair patients ahead of time for SLT

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee discussed the quality of split livers and how the quality effects allocation. They mentioned that where livers get split, either at the hospital or at the transplant centers, affect the cold

ischemic time the second liver segment has making them harder to place. The Committee did note that cold ischemic time matters less than it used to with the increased prevalence of machine perfusion. The Committee also noted that frequently when livers are split the left segment takes most of the valves which makes the right segment less useful, harder to place, and more likely to be discarded.

The Committee discussed a paired patient system called the Trotter Score system where patients are paired ahead of time for SLT to alleviate logistical difficulties once a split has occurred. For small right segments where the donor was small, this type of system may reduce difficulty placing a small right segment. One member cautioned that pediatric patients under such a system may lose access to organs if they are dependent on adult match runs as some transplant centers have less adults on their list making pairing more difficult.

The Committee discussed at length possible ways to incentivize SLT. Suggestions for SLT incentivization included:

- Prioritizing centers that specialize in SLT
- Having outcomes of SLT not count against transplant centers.
- Allowing centers that split livers to use both segments at their center.
- Creating workgroups of transplant program members to facilitate communication between regions
- Moving patients and their family's decision to accept a split to earlier in the process, prior to getting a liver offer

The Committee felt apprehensive about penalizing patients for center behaviors, but they did note that given the specialization required to do SLT it may be justifiable. Only centers with extensive experience can make use of right segment graphs that are often much harder to use. The Committee also considered making such centers go through an application process like the application process transplant centers must go through for living donor transplantation.

When discussing the option to not have outcomes for SLT count against transplant centers, the Vice Chair noted that this may increase the likelihood of centers splitting livers and realizing that the outcomes are nearly the same as whole liver transplants.

When discussing the option to change when split liver acceptance is discussed with the patient, one member noted that having the conversation earlier in the process would help patients make informed decisions and the Chair noted this may result in an increase in SLT.

Next steps:

- Decide on donor characteristics.
- Consider removing SLT from center outcomes.
- Decide what the rules should be for the allocation of the second segment resulting from a split.

4. Continuous Distribution: Travel Efficiency

Presentation Summary

The goal of the travel efficiency attribute is to reduce the distance traveled, not the cost associated with travel. One option for addressing this attribute is to use an approach like what kidney and pancreas did in creating a linear graph with an inflection point for when centers tend to switch from driving organs to flying them. The shape of the graph needs to be addressed and the weight for this attribute will be decided with information from the Massachusetts Institute of Technology (MIT) simulation.

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee felt that the inflection point should be 150 miles, which is about 3 hours of drive time, the point where most centers decide to fly the organ. The Vice Chair noted that transplant centers differed in their decision on when to fly over driving differed based on if the centers were in urban or rural areas. The Committee discussed other options than using miles traveled but felt that everything else considered so far was too difficult to implement, especially given that this attribute would be weighted low in assigning allocation points.

The Chair noted that this attribute was designed to be a tie breaker between patients with similar scores and that the acuity circle system already in place is similar. This new attribute under CD will make boundaries a bit softer which was the primary goal of transitioning to CD.

Next steps:

The Committee will look at new options for how the line on the graph degrades after 500 miles out to 3000 miles and finalize the inflection point.

5. Working Lunch: NLRB Project Update

Presentation Summary

The Committee was presented with highlights of recommended changes made to the guidance on various conditions including:

- Hepatic Hydrothorax
- Neuroendocrine Tumor
- Hereditary Hemorrhagic Telangiectasia
- Small for Size Syndrome
- Late Vascular Complications

Most of the changes to guidance for these items were to clean up the language, provide greater clarity on criteria needed for the exceptions, and provide guidance on exception points. The exception being Late Vascular Complications which was merged with Ischemic Cholangiopathy guidance.

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee discussed Small for Size Syndrome guidance and when the patient should get priority points noting it could be given at diagnosis, at the 7-day mark, or at the 14-day mark. The Committee also wondered if MMat-3 was appropriate for the condition or if it should warrant MMat or possibly even higher given the mortality rate for Small for Size Grade C patients.

The Committee also discussed the Late Vascular Complications changes. The Chair pointed out some language could be simplified by changing a line to say, “abscesses and biliary strictures that are refractory beyond six months of standard intervention”. Other members noted that the title was a bit confusing and that perhaps Late Vascular Complications should be relabeled as Ischemic Cholangiopathy. One member also pointed out that the way criteria reads, a patient with a refractory anastomotic stricture who was percutaneous transhepatic biliary drainage (PTBD) dependent could get this exception and should be updated to specify non-anastomotic strictures.

Next steps:

The NLRB Subcommittee will continue to revise guidance language and report back to the Committee.

6. Non-Standard and Standard Score Recommendation Data Requests

Presentation Summary

The data request analyses 13 non-standard exception diagnoses with forms submitted between July 1, 2022, and December 31, 2023. The analysis used most the recent form for each person's unique diagnosis. Around 74% of all the forms submitted were approved, the rest were denied or withdrawn. Hepatic Encephalopathy is of special interest because it shows 86 approvals which is incredibly high for that diagnosis.

The second data request was an analysis of exception request forms for the nine standard exceptions submitted between February 1, 2020, and February 28, 2023. HCC accounts for almost 92% of the forms in this analysis. Of these forms around 40% were initial requests, 57% were extension requests, and 3% were appeal requests. Policy requests are almost always automatically approved. This analysis showed transplant rates for each of nine standard exceptions. HCC had the highest number of transplants at 3,965 with a transplant rate of 58.7 per 100 person-years.

Summary of Discussion:

Decision #1: The Committee decided to request data for non-exception patient's transplant rates with MELDs of 27,28, and 29.

Decision #2: The Committee decided to request data regarding the narratives for the approved Hepatic Encephalopathy non-standard exceptions.

The Committee expressed shock that non-standard Hepatic Encephalopathy exceptions were getting approved at such a high rate and requested that the narratives for this diagnosis be reviewed so the Committee could better understand why the number of approvals was so high. The Committee also discussed reviewing the criteria for the Hepatic Encephalopathy exception and making it more stringent.

When reviewing the standard exception data, the Committee felt the results for each of the nine standard exceptions were appropriate. The Committee felt this data would be important for deciding if they should adjust MMaT and if the adjustment should be made based on transplant rate or dropout rate. One member did note this data was before pump technology changed the transplant landscape.

The Committee felt that HCC should be the standard by which to measure the transplant rate for other exceptions. Several committee members noted that the HCC exception has a built in six months wait period before the patient gets exception points which makes it difficult to use HCC as a standard by which to measure other exceptions.

One member noted the guidance for primary hyperoxaluria may need to be updated because small interfering ribonucleic acid (siRNA) treatment is now available and that perhaps that treatment needs to be tried before an exception is granted. Another member noted similar concerns with cystic fibrosis.

Next steps:

- Review the data requests for non-exception patient's transplant rates and narratives for approve hepatic encephalopathy nonstandard exceptions once they are complete.
- Review policy language for primary hyperoxaluria and cystic fibrosis.

7. Update: HCC Stratification Subcommittee

Presentation Summary

The Committee previously decided to consider an attribute that stratifies HCC candidate priority. An HCC Subcommittee has been formed to determine how this stratification might be achieved. The consensus is that current HCC priority is appropriate relative to other transplant candidates so to stratify the HCC population will require removing some priority from some members of this population to give to other members. One potential way to stratify the HCC population is benefit versus urgency. Another possible solution for stratification is a time dependent point assignment system. The Subcommittee will bring recommendations back to the Committee in December.

Summary of Discussion:

No decisions were made regarding this agenda item.

The Vice Chair asked if the medical aspects of the patient should be considered alongside the benefits and urgency as there was some feedback in public comment about this. One Subcommittee member mentioned that most if not all the proposed models for HCC stratification include MELD which would capture this concern.

The Subcommittee Chair noted that HCC stratification could be very complicated but that there were simpler models for stratification. They also noted that the OPOM model has been considered for this stratification process, but that MELD is the more likely choice.

One member asked how dynamic this stratification system would be. The Subcommittee responded that it has yet to be determined, but it is one of their considerations as they review potential models for stratification.

Next steps:

8. OPTN Multi-organ Transplantation Committee Update

Presentation Summary

The current process for organ allocation has OPOs run 10 different match runs and they must follow the order of those match runs but there is no real guidance how what order they work through those match runs. For multi-organ donors OPOs generally place thoracic organs first, then abdominal organs. Kidneys may be placed with the heart, lung, or liver which means there are fewer high-quality kidneys available for kidney only or kidney pancreatic patients. Furthermore, access to transplantation for candidates that need multi-organ transplants is relatively small because there is such a small pool of available organs.

The multi-organ allocation policy proposal's purpose is to promote equitable access to transplantation among multi- and single-organ candidates in a consistent and efficient manner. The current solution is to get a product that will guide OPO's through the allocation process by generating an allocation plan that guides the user between the ten different match run lists.

Summary of Discussion:

No decisions were made regarding this agenda item.

There was some concern raised about how Multivisceral patients fit into the proposed algorithm as they are a unique patient group. It was noted that there is still an ongoing discussion about how to work in this patient group into the most current draft of the algorithm.

The Committee voiced support for the project and felt this project would convert well to continuous distribution as more organs shifted to that new allocation system.

Next steps:

There are no next steps for this agenda item at this time.

9. Continuous Distribution: Exceptions & MMaT

Presentation Summary

The Committee has discussed how to translate priority and exceptions into the continuous distribution model. So far, they have agreed on aligning condition-associated priority (standard exceptions) in the medical urgency score attribute and utilizing MMaT/ Median PELD at Transplant (MPaT).

The current proposed graph for Medical Urgency alignment has higher MELD scores getting a greater percentage of Medical Urgency Points.

Summary of Discussion:

Decision #1: The Committee decided to request data for MELD scores around the median for exception and non-exception patients.

The Vice Chair asked if the Committee should consider removing MMaT awarded for exceptions and instead translating each exception into a MELD score because exceptions have been relatively unpopular with the community. The Chair noted there would be some advantages to that but that the data shows the MMaT route seems to be working well.

One member noted that it is possible to rename exceptions under continuous distribution which might help with community perception and the Chair agreed and said that under continuous distribution these exceptions will be conditions associated with priority rather than exceptions. Another member noted that the Committee can share the data on the effectiveness of MMaT and the results for patients with and without exceptions to show the community the system works well for both patient populations.

The Committee noted that the median meld will likely change as the prevalence of machine perfusion continues to grow. One member noted that in using median MELD the Committee will need to periodically review the medical urgency score and recalibrate it to accommodate for changing conditions.

Next steps:

- Review the MELD score data once available.

10. Open Forum

Presentation Summary

There was no presentation for this agenda item.

Summary of Discussion:

No decisions were made regarding this agenda item.

The Committee discussed the single organ acceptance policy. They noted that the policy was the result of late turn down times. These late turn down times made it difficult for OPOs to reallocate organs which caused organs to be discarded because they were no longer viable. The Committee acknowledged

this was a problem and that some within the liver community had exacerbated the issue. The Vice Chair specifically noted that it was the Committee's responsibility to try and correct those behaviors within their community. The Committee shared instances of losing Status A1/High MELD patients under the new policy. They cited uncertain operating room (OR) times as the cause under this new policy. Several Committee members acknowledge the difficulties with the timing of the OR due to a variety of factors.

The Committee noted two other issues that create time constraints for them. The first is that thoracic organs are allocated before abdominal organs which can delay liver transplantation. The second is that there is currently a lack of technology available to let a transplant center determine if a liver is a good match for their patient without physically seeing it. Under the new policy of single organ acceptance and the time constraints liver transplant centers experience, their sickest patients (Status A1/High MELD) do not have enough time to wait for a second offer if the first liver is not a good match.

The Committee wanted to see if there was any quantitative data that confirmed their experiences but the report on the single organ acceptance policy is not scheduled to be out till the end of November. They considered submitting their own data request for further investigation but acknowledged that with the policy having been in place for a short time and the fact that Status A1 and High MELD patients are a small portion of the population that needs transplantation, the numbers likely would not show much.

The Committee then considered writing a memo to the OPTN board with their concerns and experiences as well as some potential suggestions for addressing the situation without overturning the single organ acceptance policy. The options that were discussed included:

- Allowing transplant centers to hold two livers for Status A1/High MELD patients until the OR time is set.
- Not being locked into a liver offer until the OR time is set.

Next steps:

The Committee will consider discussing this topic in future meetings.

Upcoming Meeting

- November 1, 2024,

Attendance

- **Committee Members**
 - Scott Biggins
 - Shimul Shah
 - Aaron Ahearn
 - Allison Kwong
 - Neil Shah
 - Chris Sonnenday
 - Joseph DiNorcia
 - Mike Kriss
 - Erin Maynard
 - Cal Matsumoto
 - Vanessa Cowan
 - Vanessa Pucciaerelli
 - Colleen Reed
 - Kathlean Campbell
 - Tovah Dorsey-Pollard
 - Shunji Nagai
 - Lloyd Brown
 - Omer Junaidi
 - Christine Radolovic
 - Marina Serper

- **HRSA Representatives**
 - Jim Bowman

- **SRTR Staff**
 - Avery Cook
 - Katie Audette

- **UNOS Staff**
 - Emily Ward
 - Susan Tlusty
 - Cole Fox
 - Ben Schumacher
 - Jesse Howell
 - Betsy Gans
 - Niyati Upadhyay
 - Kaitlin Swanner
 - Carson Yost
 - Alex Carmack
 - Laura Schmitt
 - Ethan Studenic
 - Robert Hunter