

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
November 2, 2018
Chicago, IL

Julie Heimbach, MD, Chair
James Trotter, MD, Vice Chair

Introduction

The OPTN/UNOS Liver and Intestinal Organ (Liver) Transplantation Committee met in Chicago, Illinois on 11/2/18 to discuss the following agenda items:

1. Operations and Safety Interview Data
2. Review Regional and Society Comments
3. Public Comment Feedback on Broader-2-Circles (B2C) v. Acuity Circles (AC)
4. Public Comment Feedback on Sharing Thresholds and Circle Sizes
5. Public Comment Feedback on Hawaii and Puerto Rico Variances
6. Public Comment Feedback on Pediatric Allocation and Other Issues
7. Vote on Proposal to Send to Board of Directors (BOD)
8. Other Significant Items

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

1. Operations and Safety Interview Data

Data summary:

The OPTN/UNOS Operations and Safety (Ops and Safety) Committee conducted a questionnaire of 54 organ procurement organizations (OPOs) and ten transplant hospitals that asked about each organization's travel practices. Each organization submitted one response to the questionnaire.

Summary of discussion:

UNOS staff presented the relevant data from the questionnaire. To conduct the questionnaire, members of the Ops and Safety Committee interviewed key personnel from OPOs and transplant hospitals. There is potential bias in the data because the responses are reflective of only one person's perspective at each organization.

Some members of the committee questioned the accuracy of the responses. The Chair stated that the data indicates that there is large variation in the perceptions of OPO and transplant hospital travel practices.

OPO and transplant hospital interviewees reported a wide range in the distance (in miles and minutes) that their organization would travel to procure a liver. The responses also showed a wide range in the percent of livers transported by air across each region. A separate report prepared by the Scientific Registry of Transplant Recipients (SRTR) showed large variation in the percent of livers currently flown in each Donation Service Area (DSA). The SRTR report indicated that the percent of livers currently flown in each region ranges from 30% to 60%. Areas with no liver program could be flying for 100% of their livers. All of this data indicates that travel practices vary widely across the nation. In the questionnaire, the median percent of livers flown by OPOs was approximately 50%. A committee member reminded the group that there are roughly ten OPOs with their own recovery teams so they can fly donors instead of procurement teams, which is an important distinction for traveling purposes.

The questionnaire also asked about each organization's experience with the new lung allocation policy, which went into effect in December 2017 and involved broader distribution. The respondents reported a variety of experiences with the new policy. Committee members questioned the usefulness of the questionnaire data because there has been more objective data collected on the lung allocation model. UNOS staff clarified that the OPTN does not collect travel or cost data. They also stated that the Ops and Safety Committee quickly put together the questionnaire to help answer some of the questions about fixed-distance allocation and noted that there is a need to do more detailed data collection and analysis in the future.

The committee then discussed the data in the six month report for the new lung allocation model. Although there are differences in the distribution models and respective data for lungs and livers, the report could be used to justify the decisions made by the Liver Committee because it shows that there are geographic limits to distribution.

One committee member stated that since implementing the new lung allocation model, his/her transplant hospital has gone from 30% to 70% imported lungs; the median costs of organ acquisition went from \$35,000 to \$70,000; the volume of transplants stayed the same; and the patient population did not change. Another committee member noted that in New York, the costs have decreased from \$75,000 to \$55,000.

The committee discussed the costs associated with importing and exporting livers. A committee member noted that OPOs can charge different rates for imported organs versus exported organs. Some committee members also mentioned that OPOs are charging more for imported and exported organs. However, an OPO administrator on the committee noted that his/her OPO does not charge more. UNOS staff stated that the increased charge for imported/exported organs occurs prior to the updating of insurance policies, so it is not a long-term issue.

Next Steps:

The committee will consider the data presented and use it, when possible, as justification.

2. Review Regional and Society Comments

Data summary:

UNOS staff presented data on the public comments submitted regarding the "Liver and Intestine Distribution Using Distance from Donor Hospital" proposal.

Summary of Discussion:

Most of the comments were submitted by transplant hospitals, patients, and members of the general public. Many comments came from Texas, New York, California, and South Carolina, while other states also submitted a significant number of comments. UNOS staff reminded the committee that the policy making process is not a popular vote.

Approximately 40% of respondents opposed both B2C and AC, approximately 10% supported both models, approximately 10% supported B2C and opposed AC, and approximately 35% supported AC and opposed B2C.

UNOS staff presented data on public comment feedback at the state level. There was mixed support for the two models when looking at framework preference by state, where each state counts as a single vote. A committee member commented that the data showing the amount of support in either direction is relevant, but it is more important to consider the substantive and constructive comments. Nonetheless, it is important to see that there is not unanimous support in any direction.

One committee member stated that he/she believed that people may have thought that B2C entailed broader distribution than AC because of the use of the word “broader” in the nomenclature.

UNOS staff informed the committee that public comment closed at 5:00 PM Eastern Time on November 1, and the data presented was finalized around 10:00 PM on November 1. The short public comment period and turnaround were due to the committee’s request for additional modeling. Prior to the meeting, UNOS staff distributed a document with all submitted comments to the committee members. UNOS staff also reminded the committee that not every respondent answered every question.

There were some comments that were mistakenly taken off the OPTN website, but they will be put up. One comment did not meet the OPTN standards. The individual that submitted the comment was contacted and edited the comment.

UNOS staff presented data on state preferences where each state was weighted by the number of transplants in the state. From this perspective, there was more support for AC. One committee member noted that similar states opposed both models and supported B2C. Another committee member stated that it is important to look at the data this way (where responses are weighted by number of transplants) because it shows the number of patients that will be affected.

The Chair presented the feedback from the regional webinars. A committee member noted that his/her regional webinar did not seem to be well attended and participants were generally confused by the proposal. The Chair noted that there were fewer comments during the regional webinars than expected, but this may have been due to the awkwardness of speaking during a webinar or because the webinars occurred during the work day. Although there has been significant public feedback overall, there has been less regional feedback on this proposal. Another committee member noted that regional members did not know that they would be voting on the proposal during their regional webinar. Committee members were critical of the regional feedback process for this proposal. In the feedback that was submitted, there was a low vote count and no clear consensus in most regions.

The Chair then presented the comments from transplant societies.

The American Society of Transplantation (AST) did not support either model, but preferred B2C with a Model for End-Stage Liver Disease (MELD)/ Pediatric End-Stage Liver Disease (PELD) threshold of 35 and a pediatric MELD/PELD threshold of 32. They were concerned about flying, higher costs, increased risk, and more discards. They supported the variance for Puerto Rico. They wanted additional stratification of pediatrics in modeling and monitoring and were concerned that the new policy would dis-incentivize splitting.

The American Society of Transplant Surgeons (ASTS) supported building a population-based model that could be adjusted incrementally to minimize unintended consequences. They also suggested studying the impact of distribution circles on listed patient survival, transplantation rates, transplant MELD, as well as the impact of increased travel on success rates and associated costs.

The Association of Organ Procurement Organizations (AOPO) was generally supportive of the process and believed that the committee is looking to provide an incremental change that meets the Final Rule and maximizes utilization. They were concerned that broader sharing will result in an increased risk of out-of-sequence allocation and that recipient complications will make sequential reallocation more challenging. The Chair noted that data for out-of-sequence allocations exists for Share 35 and can be used as justification if needed. AOPO also wanted

improvements to DonorNet, some of which are already in place. They supported the pediatric changes and extending the variance to Puerto Rico.

NATCO preferred B2C at a MELD/PELD threshold of 35 and 150/250/500 nautical mile (nm) circles. They did not want anyone other than the transplant community to make allocation policy. They would have preferred that the committee considered population-adjusted circles, which might have alleviated some concerns about geographic inequities.

Studies of Pediatric Liver Transplantation (SPLIT) supported the pediatric changes.

The law firm representing the plaintiffs in *Cruz et al v. U.S. Dept. of Health and Human Services*, (S.D.N.Y 18-CV-06371) submitted a comment stating their belief that B2C prioritizes geography too much. They also supported AC, although the letter was not favorable in general.

The Chair reiterated that the most important thing the committee can do is to provide justification for the decisions they make so that their reasoning can be referenced in any future legal proceedings.

A committee member noted that the litigants used waitlist deaths as part of the rationale for their opinion, but the SRTR used a different definition for waitlist mortality in their report than what program directors typically use. The SRTR modeling did not account for candidates that were removed from the waitlist for being too sick in their waitlist mortality calculation. By using this definition, the modeling showed a reduction in transplants and a decrease in waitlist deaths in some areas. The Chair told the committee that even though this definition is different than what they are used to, SRTR also modeled the current allocation system using this definition so the comparison between the current system and any of the proposed systems remains pertinent.

The SRTR cannot model the number of people that are removed from the waitlist because the Liver Simulation Allocation Model (LSAM) does not provide the reason for why candidates are removed from the waitlist. They do have this data for real patients, but not for simulated patients. The SRTR could provide modeling on total pre-transplant deaths if the committee would like, although this probably does not change waitlist outcomes. The SRTR has been modeling waitlist deaths in this way for a number of years. The committee remained critical of the SRTR's definition of waitlist deaths and maintained that it is not the proper definition. In response to the comment that a decrease in waitlist deaths cannot occur if there are fewer transplants in a DSA, UNOS staff noted that it could also be the case that transplants are going to sicker patients, so fewer transplants could translate to a decrease in waitlist deaths. A committee member also noted that there are many factors that impact waitlist death (besides MELD) that vary across the nation, including rates of hypertension, diabetes, etc. Because of this, some places have high rates of transplant but also have high waitlist mortality.

Indiana University Health, The University of Kansas Health System, Vanderbilt University Medical Center, and Washington University in St. Louis/Barnes-Jewish Hospital Transplant Center collectively submitted a letter to the committee as public comment. They suggested using the Cumulative Community Risk Score (CCRS) to measure the impact of the models. They did not support either model. They focused on the idea that the Final Rule has many other components that the committee is not paying attention to, such as efficiency, organ wastage, and decreasing disparity in access. They objected to using median MELD at transplant (MMaT) in the DSA to measure disparity because DSA should not be used even in this way. In their view, MELD does not reflect mortality risk.

The committee continued to discuss the issue of waitlist mortality. There are differences in waitlist mortality for the same MELD/PELD score by region, although the reasons for these differences is not clear. A committee member stated that the variance in MMaT for non-exception patients across the country is almost 21 points, which is a large disparity. There was

disagreement among the committee members over how exception patients influence the MMaT, although there was agreement that exception patients are not as impacted by geographic disparity. There is large variation in non-standard exception scores across the country, which is why the committee is in the process of implementing a National Liver Review Board (NLRB) as approved by the OPTN/UNOS BOD in December 2017.

The Chair presented SRTR data on the MMaT by DSA for each OPO. The lowest MMaT for an OPO is 24 and the highest is 33. There is also wide variation within the same DSA. One committee member noted that MMaT is an imperfect metric because it is dependent on a multitude of factors. The committee member suggested using other metrics, such as offer rate or a candidate's likelihood of still being on the waitlist after a certain period of time, to measure program performance.

The Chair reiterated that the way SRTR calculated waitlist mortality was different than the way waitlist mortality is calculated at the transplant programs. However, the data is still useful in examining the change between current waitlist mortality and the proposed policies. SRTR sent the committee members new data that modeled total pre-transplant deaths, as previously discussed. A committee member also sent a document comparing LSAM waitlist mortality data to UNOS waitlist mortality data. The LSAM results are not predictions of actual values, but instead are important in showing the relative change between the different scenarios. The same idea should be applied to the percent of livers being flown. The modeling should be used to understand the magnitude of change between scenarios, as the point prediction might be inaccurate. The Chair ended the discussion by stating that there are differences in how waitlist mortality is calculated, and the committee must consider these differences going forward.

Next steps:

The committee will consider the data provided and public comments in the policy making process.

3. Public Comment Feedback on Broader-2-Circles (B2C) v. Acuity Circles (AC)

Summary of Discussion:

UNOS staff identified the common themes throughout the public comment period. The Chair reminded the committee to continue thinking about sources of objective evidence for each issue.

One common theme was concern about an increase in discarded organs due to more travel. The Chair stated that the committee might be able use the data from Share 35 to provide evidence for increased travel causing more discards. Another theme identified in public comment was concern about additional cold ischemic time (CIT), also due to more traveling. The Chair stated that current data indicates that after eight hours of CIT, the quality of the liver decreases. Other committee members disagreed with this statement and instead stated that the quality of the donor pool is going down and the percent of livers transplanted prior to five hours of CIT is increasing. A committee member suggested using the decreasing quality of the donor pool as justification for the concern about increased CIT.

Other themes identified in public comment were concerns about higher costs and increased risk for recovery teams.

A committee member shared the results of Share 35 after two and three years. The variance in MMaT increased, the discard rate decreased, there was no change in CIT, post-transplant survival was not affected, and the number of transplants went up (although this is more likely due to an increase in donors).

A committee member clarified that CIT and transport time are not the same thing. There are factors beyond transport time that affect CIT. Also, behaviors will change to reduce CIT when faced with longer transport time. It is also important to recognize that some high quality livers can have a longer CIT and flying to recover a liver is typically done only when the recovery team knows they are getting a high quality liver.

A committee member noted that there is work being done to better quantify the increased risk of flying on procurement teams. The committee member also mentioned that there are many “near misses” that did not become accidents but should be recognized. The committee also discussed that more travelling and flying will force programs to utilize more manpower, and the opportunity cost of sending a procurement team a far distance for a marginal liver may not be worthwhile. This issue is more important at small programs, who may only have two or three surgeons.

A committee member, who is an OPO administrator, noted that his/her OPO does all of the recoveries in his/her region and the transplant programs seem to be satisfied with this arrangement. Another committee member noted that in his/her region, they offer local recovery for every liver and are almost always turned down. One of the major issues with local recovery is that the skill level of the recovering surgeon is often unknown and transplant programs do not like this unknown. The committee suggested using live video technology so that the transplant program can observe and comment on the organ recovery process, but this is more of a long-term solution.

The Chair presented common themes in public comment related to disparity. These themes were:

- Desire to reduce variation in MMaT, especially in non-exception candidates
- Desire to address long wait time in high MMaT areas
- Concerns that disparity creates a system in which patients with the means to move or to list in another state have a better chance of transplant
- Desire for the sickest patients to get transplanted first
- Belief that organs are a national resource although this belief is not held by everyone
- Desire to prioritize offers to populations that have higher waitlist mortality rate.
- Desire to prioritize offers to populations with a higher incidence of liver disease
- Desire to prioritize offers to populations that have less access to the waitlist
- Belief that MMaT is not appropriate way to measure disparity because MELD doesn't predict mortality risk

Other comments suggested ways to address disparity. These comments were:

- Increase transplant rates instead of changing allocation policy
- Belief that median MMaT is driven by listing and acceptance practices
- Belief that the solution to disparity is additional education in areas with lower donation rates
- Create OPO performance goals
- Education for the general public

The Chair then presented common themes in public comment related to unintended consequences. The Chair noted that large changes in allocation policy could have many unintended consequences, a possibility that the committee could use as justification for whichever model they choose. Common themes in public comment related to unintended consequences were:

- Concern that additional costs would cause smaller programs to close
- Desire to minimize the amount of change

- Concern that donors will be reluctant to donate if their liver will not stay in the local community

Committee members disagreed on the relevance of the reluctance of individuals to donate if their liver will not stay local. Some committee members said they had not heard this concern raised in their DSA, while others had heard it. UNOS staff noted that HRSA has conducted national surveys related to this concern and, while some people do prefer their organs to stay local, the surveys have consistently shown that donors and donor families want their organs to go to the sickest patient first.

A committee member noted that some populations, especially minorities, feel a lack of access to obtaining a transplant and are therefore less likely to donate. If certain populations do not feel like they are part of the recipient pool or they mistrust the medical system, then they are less likely to donate.

The committee discussed the issue of regional variance. The committee must be thoughtful in how the new allocation model is communicated, especially to the donor community. For example, it will not resonate with people if the proposal says that places like California are disadvantaged relative to places in the Southeast, even if this is true in the case of MMaT. Low donation rates exacerbate this issue. OPO performance is part of the reason for the variance in donation rate, but the variance is also caused by differences in the cause of death. For example, the donation rate is higher in the Southeast because more people die from stroke and at a younger age. Another committee member noted that rural populations across the nation have less access to the medical system overall. A committee member sympathized with places with a high prevalence of acute liver disease and suggested focusing on making sure these people get on the waitlist.

A committee member observed that many of these arguments were the same ones made during the development of Share 35. However, none of the smaller programs have closed due to Share 35. Additionally, it is true that populations across the nation have different levels of access to the healthcare system and different rates of certain diseases, but the fact remains that the single largest determining factor in getting a liver transplant is where the candidate is listed. There should be efforts to increase access, but the purpose of the committee is to allocate the livers available to the people on the waitlist. However, the committee does need to consider unintended consequences and should not disenfranchise any population.

A committee member stated that avoiding unintended consequences is particularly important to this discussion because the implementation of the NLRB could also lead to unintended consequences and there are no rescue devices for liver patients. It is also necessary to mitigate travel, especially for smaller programs who may turn down a marginal liver if they need to fly to recover it, although it will be difficult to find objective evidence to support this conclusion. Additionally, the committee member noted that much of the evidence is based on experience, not objective data. One committee member stated that private insurance reimburses transplant programs at a higher rate so programs may target privately-insured patients for organs that they must fly to procure, thus disadvantaging those on the waitlist with public insurance.

The Chair then presented the other common themes in public comment. The other themes included a desire to decrease waitlist mortality, concern that the process is moving too quickly, and questioning how there can be a decrease in transplant numbers and a simultaneous decrease in waitlist mortality.

The committee then started discussing which model they prefer. One committee member asked why the group had not considered a model using proximity points. If they had time to consider

this, they would, but the compressed timeframe has made this impossible. The Chair told the committee that they can make tweaks to either model based on the data they have.

A committee member commented that there are ways to alter the AC model to help mitigate travel and this model prioritizes the sickest patients. It is possible to predict what will happen if the committee elects to add three MELD/PELD points to the inner acuity circle by extrapolating the data they have been given. This may mitigate some flying.

A committee member noted that most of the transplant community does not understand the AC model and it is worrisome that the committee would put out a model that most people do not understand. Another committee member stated that people are influenced by where they are from and how the new policy affects them. If the committee had more time, they could explain the policy better.

Before voting, the Chair asked each committee member to express their opinion on the models. These comments are summarized below:

- The AC model benefits the vast majority of patients. It is not perfect, but the issues of increased cost and potential program closure can be mitigated. AC does the best job at reducing MMaT variation. The charge of the committee is to do what is best for people across the nation.
- B2C is more broadly supported by the transplant community. Increased flying will be a logistical nightmare with many unintended consequences. The concerns about socio-economic status are legitimate.
- Support B2C because there is increased risk when flying, as evidenced by the plane crash that killed a number of this committee member's colleagues.
- AC is best for patients and the risks can be mitigated.
- People understand B2C better.
- There is a precedent for B2C with lung allocation.
- Region 4 has over 1,500 candidates on the waitlist and more lives will be affected than almost anywhere else. The 150 nm circle will isolate the people in Houston. The most important thing is that geography cannot preclude a patient from getting an offer. B2C will isolate a large number of patients in Texas. It is also necessary to look at the travel of the donor as well as the procurement team. Modeling shows a 10% increase in transplants in Houston, but mortality goes up.
- The job of the OPO is to maximize the gift of life that donors are giving, and AC does this.
- It does not make sense to have fixed-distance circles with variable population densities. They will need to do more in the future, so it makes sense to go with B2C which is understandable and is an incremental change.
- Older livers should stay local.
- B2C would result in the least amount of change but it has the ability to be altered based on results
- AC compensates for population density due to narrowness of the MELD/PELD bands
- National sharing should be at MELD/PELD of 18 instead of 15

A formal vote was taken regarding: which model do you prefer?

Results were as follows: B2C 11 in favor (55%); AC 9 in favor (45%)

	B2C in favor	AC in favor	Abstain
Number of votes	11	9	0
Percentage	55%	45%	0%

Next Steps:

The committee will move forward with a proposal for B2C.

4. Public Comment Feedback on Sharing Thresholds and Circle Sizes

The Chair presented information on public comment feedback regarding the sharing threshold and circle sizes. Most comments supported larger circle sizes with a sharing threshold of MELD/PELD 29 or smaller circles with a sharing threshold of MELD/PELD 35.

UNOS staff reiterated the responsibility of the committee to show why each of their decisions is necessary to make the allocation system more efficient as outlined in the Final Rule. The model that the BOD passes will probably not change for two years so that there is enough time to analyze the allocation model and appropriately adjust it, provided that there are not major unintended consequences.

Some of the themes identified in public comment regarding circle size were:

- Concerns about including water
- Concerns about making areas smaller than the current DSA
- Requests for a population-based model
- Requests to treat Alaska differently

There were a number of other circle sizes suggested but none gained much traction. In terms of justification, the committee recognized 150nm as the agreed upon cutoff for driving versus flying.

The Chair presented the themes identified in public comment regarding the sharing threshold for the 250nm circle. These themes were:

- Support for MELD/PELD 35 as this is the closest to the December 2017 proposal
- Support for MELD/PELD 29 because it appears to be an inflection point on the mortality curve and gives access to more patients within 250nm earlier
- Requests for a threshold of MELD/PELD 15
- Requests for no sharing threshold

SRTR modeled B2C at both MELD/PELD 32 and 35, so it is possible to understand what MELD/PELD 29 would look like by extrapolating the modeling for MELD/PELD 32 and 35. Some committee members were resistant to proposing a policy that had not been modeled. The committee discussed the sharing threshold extensively prior to putting the proposal out for public comment and there was support for MELD/PELD 29, 32, and 35.

A committee member proposed a new idea that would include candidates with MELD/PELD 35 or more with the Status 1A and 1B candidates in the 500nm circle.

The Chair presented what each of the sharing threshold options would look like. A threshold of MELD/PELD 35 would lessen distribution, while MELD/PELD 29 would increase distribution.

A committee member stated that the MELD/PELD threshold should have biological meaning. A threshold of MELD/PELD 32 has no biological meaning and would be difficult to justify. However, MELD/PELD 29 is an inflection point where risk of death starts getting higher. Offers should go out further for individuals with a higher risk of death.

A committee member noted that another issue is that the NLRB is not yet in place. Once it is implemented, there will be patients with different exception scores with the same condition. If the sharing threshold is set at MELD/PELD 29, there will be many patients with unequal exception scores. There needs to be a cap on exception scores that is lower than the sharing threshold. This cannot be changed until the exception patients cycle through the NLRB, so there will be a disparity for three months. A committee member mentioned that hepatocellular carcinoma (HCC) patients will be transplanted at a higher rate with B2C and the NLRB, but the Chair stated that this effect is not known.

HRSA clarified what they are requesting from the committee. HRSA does not intend to direct the OPTN on what the policy should be because there are many factors that must be balanced. HRSA directed the OPTN to work with the public to create an allocation policy that considers all of the factors described in the Final Rule. When the committee is setting a geographic boundary, the committee must provide evidence for why the boundary is required. No policy is going to be perfect and stand in perpetuity, but the onus is on the OPTN to justify the decisions the committee makes.

A committee member noted that the policy will be updated and improved over time based on the data so they should start at MELD/PELD 32 because they have modeling for this threshold. Another committee member discussed the MELD/PELD cliff that the threshold would create in B2C. For example with a threshold of MELD/PELD 32, a candidate with a MELD/PELD of 31 who is 155 nm from the donor hospital will be skipped over by a candidate with a MELD/PELD of 16 that is 145 nm from the donor hospital. This is a 40% difference in mortality risk. A threshold of MELD/PELD 29 would lower this cliff from MELD/PELD 31 to MELD/PELD 28, which is still significant but less dramatic.

The Chair presented data on public comment feedback about the sharing threshold. Most commenters supported MELD/PELD 29, followed by MELD/PELD 35, and finally MELD/PELD 32. The Chair pointed out that more than half of the BOD are not physicians so they will have a different perspective than the committee. Patients supported the lowest threshold. The committee discussed the ability of MELD/PELD to predict mortality and there was agreement that it was valid up to a certain point, but it is not perfect. The committee is tasked with balancing the threshold with efficiency, especially regarding travel. A committee member noted that MELD/PELD scores will likely lower with time, but the Chair stated that this is not necessarily true.

A committee member reiterated his/her proposal to move candidates with MELD/PELD 35 and above to the 500 nm circle after the Status 1A and 1B candidates. In this proposal, livers would be allocated to Status 1A and 1B within 500 nm, then MELD/PELD 35 within 500 nm, then MELD/PELD 32 or 29 within 250 nm and so on. The proposal was seconded. Allocation would still go to Status 1A and 1B first and then would be ordered by MELD/PELD within the 500 nm circle. Nothing would change for pediatric candidates. Some committee members were concerned that this would change the model too much without formal SRTR modeling. Another committee member suggested that this is similar to AC and they should just go back to AC. The percent of candidates on the waitlist with MELD/PELD 35 or more is small, so the committee does not know how much increased travel there will be. The committee member that suggested the proposal stated that candidates with MELD/PELD 35 or above have similar mortality to Status 1A and 1B, so it is not possible to justify allocating them lower on the list.

A formal vote was taken regarding: do you support this modification?

Results were as follows: 7 (37%) Yes; 12 (63%) No

	Yes	No	Abstain
Number of votes	7	12	0
Percentage	37%	63%	0%

The committee started discussing the sharing threshold again. One committee member stated that the justification for a threshold of MELD/PELD 32 is that it is an incremental change that allows for the NLRB to go into effect and can be studied over time. The Chair informed the committee that the vote on the threshold will be between a threshold of MELD/PELD 32 and threshold of MELD/PELD 29. There was no support for MELD/PELD 35. Another committee member reiterated that MELD/PELD 29 can be justified because it is the inflection point on the mortality risk curve. Many of the societies are concerned about the 10% increase in flying associated with a threshold of MELD/PELD 32.

A committee member disagreed with the notion that incremental change can be used as justification. Incremental change cannot be replaced by the idea that the committee makes no progress. Incremental change is not what is best for patients.

Another committee member asked if there is any way the AC model can be modified to mitigate the issues of travel. The committee agreed that it was not possible to do this within the allotted timeframe. A committee member noted that AC is preferable because it allocates locally first, thus minimizing travel. Additionally, if the committee alters AC to have proximity points or different band sizes, then travel could be reduced. The Chair stated that the committee already chose B2C and they cannot re-vote on B2C versus AC.

UNOS staff clarified the justification that the committee has discussed for each of the MELD/PELD thresholds. The justification offered for MELD/PELD 32 was that it is an incremental change and allows for time for the NLRB to be implemented. UNOS staff said that this justification does not relate back to the Final Rule, and will therefore be difficult to use. A threshold of MELD/PELD 32 was also modeled to have a 10% increase in travel over the current system. This can be brought back to the Final Rule, but this modeling has not been done for MELD/PELD 29. A committee member stated that they had already proposed MELD/PELD 32 to the community and changing to MELD/PELD 29 could violate the trust of the community. However, there was a plurality of support for MELD/PELD 29 when looking at public comment feedback by state weighted by transplant volume. Patients also preferred MELD/PELD 29. A committee member asked if it would be possible to predict the increase in travel for a threshold of MELD/PELD 29. The threshold of MELD/PELD 29 would add about 2% of the waitlist to the 250 nm band. A committee member suggested that proposing something that has been modeled (MELD/PELD 32) is sufficient justification. However, the Chair said that there is precedent for bringing something to the board that has not been modeled. A committee member reminded the group that HRSA is asking for justification on why travel is a relatively important consideration compared to reducing waitlist mortality. Another committee member suggested that the inflection point in the mortality risk curve is actually at MELD/PELD 25, which would only add 5% more patients to the 250 nm circle. However, this is the percentage of patients on the waitlist but not the percent that gets transplants. The Chair motioned to vote.

A formal vote was taken regarding: do you support a MELD/PELD sharing threshold of 32 or 29?

Results were as follows: 11 (55%) in favor of MELD/PELD 29; 9 (45%) in favor of MELD/PELD 32

	In favor of MELD/PELD 29	In favor of MELD/PELD 32	Abstain
Number of votes	11	9	0
Percentage	55%	45%	0%

Following the vote, a committee member put forth a motion that the model proposed by the committee be implemented at least three months after implementation of the NLRB with a cap of MELD/PELD 28 for standard exceptions. The motion was seconded. A committee member noted that it will be necessary to communicate to patients that their MELD/PELD score could go down due to the new allocation policy. The committee discussed grandfathering candidate's MELD scores over for the first three months or until there is time for their MELD scores to be readjusted. In the motion put forth, the exception cap of MELD/PELD 28 would go into effect the same day that B2C is implemented, and in the meantime the cap would be MELD/PELD 34. An exception cap of MELD/PELD 34 is in currently approved but not yet implemented policy. The committee discussed lowering the cap to MELD/PELD 28 once B2C is implemented. Implementing B2C three months after the NLRB would allow for time for exception patients to cycle through the NLRB. The cap at MELD/PELD 28 is necessary because with MMaT minus three there will still be candidates higher than MELD/PELD 29 in some areas of the country.

UNOS staff clarified that new exception scores could not go into effect all at once because moving to a model that is based on MMaT is a logistical challenge. The metadata that will be collected for exception patients when the model is MMaT-based would allow the committee to transition to a different cap. Policy states that time on the waitlist will be used as the tiebreaker between patients with the same exception score. There was some confusion as to how the new exception score would be implemented but the committee agreed to vote on the proposal to implement B2C three months after the NLRB and have an exception cap at MELD/PELD 28 when B2C is implemented. The committee will figure out the logistics of the motion at a later time. A committee member clarified that programs will still be allowed to apply for exceptions to these rules. Another committee member noted that in San Francisco, the MMaT is MELD/PELD 33 so exception patients would get a score of MELD/PELD 30, but this proposal has a cap of MELD/PELD 28.

A formal vote was taken regarding: do you support implementing B2C at least three months after implementing the NLRB?

Results were as follows: 14 (74%) Yes; 2 (11%) No; 3 (16%) Abstain

	Yes	No	Abstain
Number of votes	14	2	3
Percentage	74%	11%	16%

A formal vote was taken regarding: do you support a cap for standard MELD/PELD exceptions at 28?

Results were as follows: A majority of the committee supported the proposal.

UNOS staff clarified that this exception would only be for adult standard exceptions. There would not be a cap on pediatric exceptions.

A committee member suggested keeping organs from donors after cardiac death (DCD) that are age 60 and older within 150 nm. This could decrease travel. A committee member stated that most programs will not use DCD organs for candidates over MELD/PELD 30. This proposal would give programs an incentive to use these organs locally. The committee decided not to make this change.

UNOS staff asked about the impact of the MELD/PELD 29 threshold on blood type O donors. Currently, blood type O donors are allocated in the same classification as blood types O and B recipients who also have a MELD/PELD of 30 or higher. UNOS staff asked if the sharing threshold for blood type B recipients should also be MELD/PELD 29. These thresholds are in place for different reasons. This would be an extra line in the policy but does not change the difficulty of programming. No vote was taken.

Next Steps:

The committee will include these modifications in the policy proposal.

5. Public Comment Feedback on Hawaii and Puerto Rico Variances

Summary of Discussion:

The committee discussed extending the existing blood type variance in Hawaii to Puerto Rico. When the committee put the proposal out for public comment, they supported keeping the variance in Hawaii and did not want to extend the variance to Puerto Rico. However, public comment supported extending the variance to Puerto Rico. The committee did not originally support extending the variance because Puerto Rico is not as geographically isolated as Hawaii. There is also some sharing between Puerto Rico and Region 3. The Chair presented data on the distribution of deceased donor liver transplants by recipient blood type in Puerto Rico. The variance being discussed allocates blood group O livers first to blood group O and blood group B candidates with MELD/PELD greater than 30.

A committee member stated that extending the variance to Puerto Rico means that a blood type O liver recovered in Miami would not get offered in Miami until it went through all the different blood types in Puerto Rico. The flight from Miami to Puerto Rico is two hours. Puerto Rico has roughly 70 candidates on the waitlist. Puerto Rico has a relatively large donor pool because of high consent rates and high homicide rates. However, many of their donated organs are exported. A committee member stated that blood type O candidates in Miami should have access to blood type O livers, but the exception does make sense for Puerto Rico. The blood type O candidates in Miami would be the ones disadvantaged. A committee member expressed empathy for the overall situation of the people of Puerto Rico and mentioned how they are a disadvantaged population. Another committee member stated that although Puerto Rico is closer to the contiguous United States than Hawaii, it is still isolated. Puerto Rico does export some marginal organs to Miami. A representative from the Minority Affairs Committee noted that this idea came from his/her committee.

A formal vote was taken regarding: do you support extending the Hawaii variance to Puerto Rico?

Results were as follows: 15 (83%) Yes; 2 (11%) No; 1 (6%) Abstain

	Yes	No	Abstain
Number of votes	15	2	1
Percentage	83%	11%	6%

Next Steps:

The committee will include this modification in the policy proposal.

6. Public Comment Feedback on Pediatric Allocation and Other Issues

Summary of Discussion:

The committee then discussed their plan for liver allocation in Alaska. Alaska does not have a liver program and is geographically isolated. One option is to nationally share all of their livers, but this is not efficient because the state is roughly 2500 miles from the closest transplant program.

A committee member put forth the motion that for any donated liver from Alaska, the donor circle starts from the northwest corner of the United States. The motion was seconded. This makes practical sense because it allows for better distribution across the Northwest. UNOS staff stated that if this proposal moves forward, the committee will need to select a specific location from which the donor circle is drawn. The donor hospital location is used for two things. First, it is used to determine where candidates show up on the match run when they are being classified. And second, it is used to screen for the candidate-specific distance to travel. The committee suggested that the Seattle-Tacoma (Sea-Tac) International Airport be used for both of these purposes. UNOS staff stated that the Geography Committee looked at this same issue and they are not recommending this course of action. The Geography Committee is recommending that Alaska be treated where it is, like Hawaii. The committee agreed that if a liver program opens in Alaska, this policy will be changed.

A formal vote was taken regarding: do you support the proposal to move Alaska’s donor hospital location to Seattle-Tacoma International airport?

Results were as follows: 16 (100%) Yes; 0 (0%) No

	Yes	No	Abstain
Number of votes	16	0	0
Percentage	100%	0%	0%

UNOS staff asked the committee if the change to a MELD/PELD threshold of 29 would have an impact on simultaneous liver-kidney (SLK) eligibility policy. Current policy states that there is a mandatory share above MELD/PELD 35, meaning that when a patient with a MELD/PELD of 35 or higher is getting a regional liver, they can also get the kidney. As part of the public comment proposal, the committee proposed changing the threshold to MELD/PELD 32, but they have since changed the sharing threshold to MELD/PELD 29. The Chair asked if the liver-kidney proposal could be a separate policy so that the BOD does not reject the entire policy based on just this part. A committee member disagreed with this idea and stated that the committee should be consistent. If they separate one policy, then they should separate them all. Another committee member stated that the members of the BOD who are from the kidney community

will not like this proposal. Regardless, the BOD ultimately are the decision makers who pass policy. The new SLK policy, which went into effect in 2016, did not lead to an explosion of SLK transplants or a reduction in SLK transplants. The Kidney Committee is also looking into how often the safety net is being used.

A formal vote was taken regarding: do you support a MELD/PELD threshold of 29 for SLK allocation?

The results were as follows: 16 (100%) Yes; 0 (0%) No

	Yes	No	Abstain
Number of votes	16	0	0
Percentage	100%	0%	0%

UNOS staff clarified that this policy will be implemented in conjunction with the new allocation model.

The Chair of the committee spoke to the group about some of the metrics that will be monitored with the implementation of the new policy. The committee will monitor waitlist mortality, post-transplant mortality, transplant rate, transplant count (across race, age, etc.), community risk score, etc. The committee will also monitor the impact on exception scores. The Ad Hoc Systems Performance Committee is working on a better way of recording decline codes and reasons for declines. A committee member asked if it is possible for the OPTN or SRTR to monitor the offer rate. Offer rate is less dependent on offer acceptance practices, so it could be a good way of measuring disparity and the effect of the new policy. There would need to be a definition of what constitutes an offer. The committee will need to monitor the exception patients to make sure they are not being disadvantaged.

The committee clarified that the proposal to move allocation from Alaska to Sea-Tac includes exception patients.

7. Vote on Proposal to Send to Board of Directors (BOD)

Summary of Discussion:

A formal vote was taken regarding: do you support sending the proposal to the BOD?

The results were as follows: 13 (93%) Yes; 1 (7%) No

	Yes	No	Abstain
Number of votes	13	1	0
Percentage	93%	7%	0%

The Chair thanked the committee members for their effort in creating this proposal.

Next Steps:

The committee will include these modifications in the policy proposal. The proposal will be presented to the BOD at their meeting on December 3-4.

8. Other Significant Items

No other significant items were discussed.

Upcoming Meeting

- November 15, 2018