OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
April 8, 2019
Chicago, Illinois

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

Introduction

The Liver and Intestinal Transplantation Committee (the Committee) met in Chicago, Illinois on 04/08/2019 to discuss the following agenda items:

1. Update on Acuity Circles Implementation and HRSA Critical Comment
2. Definition of Pre-Existing Liver Disease
3. Pediatric ABO Prioritization
4. One-Year Lung Policy Change Report
5. Split Liver Variance Public Comment Proposal
6. Service Recognition and Incoming Roster
7. Existing Split Liver Variance
8. NLRB and Acuity Circles Evaluation Plan
9. Sub-Committee/Workgroup reports
10. Open Session

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

1. Update on Acuity Circles Implementation and HRSA Critical Comment

The OPTN Board of Directors (Board) approved the Acuity Circles distribution system (AC) at their December 2018 meeting. On February 13, 2019, a critical comment was submitted to the Secretary of the Department of Health and Human Services (HHS) expressing concerns about AC. The Health Resources and Services Administration (HRSA) then requested input from the OPTN in order to help inform HRSA's response to the critical comment. The OPTN's response was previously circulated to Committee members.

Summary of discussion:

The Chair updated the Committee on the critical comment. The OPTN Executive Committee responded to HRSA's request on March 27, 2019. The Committee had no further questions.

Next steps:

No next steps were identified.

2. Definition of Pre-existing Liver Disease

Prior to the meeting, a Committee member submitted a request for the Committee to discuss amending *OPTN Policy 9.1.A: Adult Status 1 Requirements* so that the definition of pre-existing liver disease can be clarified.

Summary of discussion:

In order for a liver candidate to be listed as Status 1, they must not have pre-existing liver disease. However, it is unclear if a patient has pre-existing liver disease if they have previously received a liver transplant. The question for the Committee's consideration was if having a previous liver transplant constitutes pre-existing liver disease.

The Committee member who brought forth the proposal felt that patients with a previous transplant had a liver condition but not pre-existing liver disease, and should be eligible for Status 1. For additional context, the Committee member noted that if having a previous liver transplant is considered a disease, then they are giving candidates a "disease" each time they do a transplant.

Another Committee member asked if there had been any issues with the policy in the past. The Committee member who created the proposal noted at least two instances over the past few years where the lack of specificity surrounding pre-existing live disease caused confusion. The Committee member felt that simply clarifying that previous receipt of a liver transplant does not, in and of itself, constitute pre-existing liver disease would be beneficial. Committee members noted a number of instances where this distinction was discussed when attempting to list a candidate as Status 1.

Other Committee members noted that the policy is also not clear if patients with hepatitis B who are not cirrhotic or patients with an auto-immune disease would be considered to have pre-existing liver disease. The Chair asked if the Committee wanted to consider previous transplant, hepatitis B, and auto-immune diseases in their clarification or just focus on previous transplant. The Chair stated that focusing on previous transplant would be easier to get into policy sooner, as opposed to trying to include all three.

The Committee agreed to only move forward with previous transplant. Another Committee member stated that they should be careful to not allow all candidates with graft failure or re-transplant to jump to Status 1.

The Chair stated that they will continue to work on potential policy language for this clarification and present it to the Committee at an upcoming meeting.

Next Steps:

UNOS staff and Committee leadership will draft policy language for the Committee's consideration.

3. Pediatric ABO Prioritization

In the AC policy, all blood type O and blood type B candidates (adult and pediatric) will receive offers from pediatric blood type O donors, before any offers are made to blood type A or blood type AB candidates. However, some members of the transplant community have commented that all pediatric candidates should be prioritized ahead of any adult candidates for pediatric donors.

Summary of Discussion:

The Chair asked the Committee if blood type O livers from pediatric donors should be allocated to pediatric candidates of all blood types before being offered to any adult candidates. The Chair clarified that pediatric donors are all donors under the age of 18. A Committee member asked for more data on the topic, specifically the number of blood type O pediatric donors that are transplanted into adults and the count and outcomes of pediatric candidates. The Committee member felt that it was important to know if pediatric candidates are disadvantaged because of the allocation sequence before making any change.

Next Steps:

UNOS staff will submit a data request, based on the Committee's feedback above, to better understand the issue.

4. One-Year Lung Policy Change Report

The OPTN recently published a one-year monitoring report on the outcomes of the lung allocation changes. Under the updated allocation policy, donation service area (DSA) was removed from lung allocation, similar to the soon-to-be-implemented AC policy.

Summary of Discussion:

UNOS staff presented the one-year monitoring report. The new lung allocation policy was implemented on November 24, 2017. In the updated policy, DSA was replaced with a 250 nautical mile (NM) circle around the donor hospital. There were no regions used in lung allocation.

The report examines the cohort of patients from one year prior to November 24, 2017 and the cohort from one year after November 24, 2017.

There were no changes in the waitlist by diagnosis group. Lungs are allocated using the lung allocation score (LAS). More urgent patients have a higher LAS. The death rate per 100 patient years on the waitlist increased for candidates with LAS greater than 70, but it was not a statistically significant change. The death rate per 100 patient years for candidates with an LAS between 60 and 70 significantly decreased.

There were no changes in the number of transplants by diagnosis group, procedure type, donor type, or blood type. There was no change in transplant rate by diagnosis group or LAS group.

The number of deceased donor lung transplants increased in some regions and decreased in others. There were 80 more transplants in the post era than the pre era, but this is probably due to increased transplantation overall.

The number of transplants for high LAS candidates increased, while there was a decrease in transplants for low LAS candidates.

There was an almost 2.5 point increase in the mean LAS at transplant. Once DSA was removed from allocation, there was more sharing within the 250 NM radius but less sharing between 250 NM and 500 NM. There was a decrease in the number of transplants within the DSA but an increase in regional and national sharing.

The majority of programs did equal or more transplants in the post era as compared to the pre era. Most small volume programs did similar numbers of transplants. Medium volume programs saw a drop in the number of transplants.

The time from first electronic offer to cross-clamp for deceased donors increased by one hour. There was also a statistically significant increase in cold ischemic time, but the increase was only 13 minutes.

Thoracic organs are rarely recovered and not transplanted, so the discard rate is low. Therefore, they focused on utilization rate, which is the number of lung donors out of the total number of organ donors. There is large variation among regions in utilization rates. However, there was a slight decrease in the utilization rate across the nation. A Committee member asked if changes in staffing could impact utilization rate. UNOS staff stated that staffing changes could impact the rate, but it is not something they tracked.

A Committee member asked if they tracked transportation data. UNOS staff stated that this is not tracked. A Committee member asked if there is any data on post-transplant outcomes. Because this is the one-year report, there is no data available on post-transplant outcomes yet. There will be information on post-transplant outcomes in the next report. A Committee member asked if there were any negative aspects of the policy change. UNOS staff stated that increased

flying and costs were two common themes heard from the community. The OPTN does not currently collect data on costs or transportation. A Committee member noted that it is important to track this data if possible. A Committee member asked what the OPTN Thoracic Committee felt about the data report. The Thoracic Committee Vice Chair said that their Committee felt relieved by the data. A Committee member asked if the Thoracic Committee had thought about the next steps in updating lung allocation. The Thoracic Committee will be the first to consider continuous distribution.

Next Steps:

No next steps were identified.

5. Split Liver Variance Public Comment Proposal

The Committee put out a proposal titled, “Split Liver Variance,” during the spring 2019 public comment period. The intent of the proposal was to increase the number of split liver transplants.

Summary of Discussion:

The proposal was out for public comment from January 22, 2019 to March 22, 2019. During that time, there was robust public comment at regional meetings and through the OPTN website. The Committee was sent a document with all public comments for review prior to the meeting.

The variance was originally proposed as a closed variance for Region 8, but the Board supported opening it up for all regions to participate. The Executive Committee then further modified the proposal by making it an open variance for any individual program to participate, as opposed to entire regions.

Support for the variance was mixed at regional meetings. However, some regions were not opposed to the variance entirely, but were opposed to the variance being open to all programs. The Chair presented data on the public comments submitted by individual commenters.

There were also four amendments offered at regional meetings. Region 3 put forth an amendment to have the variance only apply to splits with two adult candidates. Region 10 supported limiting the variance to hemiliver splits. Region 9 proposed an amendment to make the variance the same as the current split liver variance. Region 11 proposed an amendment to remove the requirement to offer the remaining segment to Status 1 and model for end-stage liver disease (MELD) > 32 candidates listed at transplant programs within 500 NM of the donor hospital. The Chair noted that many of the Status 1 candidates probably already saw the original offer, so it is unlikely that they would then accept a portion of the liver. However, if the first Status 1 candidate on the match run accepted the offer, then none of the remaining candidates on the match run saw the original offer. The Chair noted that similar feedback came in Region 7.

A Committee member stated that there are not many programs doing full left/right splits and the outcomes of the few procedures that have been done were not great. The Committee member felt that the variance should not be limited to full left/right splits.

A Committee member asked how the variance would function without regions. A Committee member supported opening the variance to the entire nation. The Committee member noted that many pediatric candidates are granted high exception scores and receive offers for livers that are then split with the pediatric candidate receiving the left lateral segment and the right tri-segment going to an adult candidate. The Committee member felt that the programs using the variance would use this situation to get organs for their adult candidates. Another Committee member felt that pediatric candidates are not over-prioritized by their high exception points.

Another Committee member stated that if the transplant program is able to transplant a right tri-segment into an adult, they should be able to transplant the left lateral segment into a pediatric candidate at their program. However, if the index candidate is a pediatric candidate that receives the left lateral segment, then the right tri-segment should be offered out to the entire match run because this segment is often accepted. Another Committee member noted that many programs are cutting down livers for pediatric candidates instead of splitting the liver and offering out the second segment. A Committee member asked how many cut-downs have occurred.

A Committee member noted that there are too many back table splits and the Committee should mandate in situ splits. Other Committee members felt that this is not something the Committee could mandate. Committee members discussed how often they have noticed the second segment of split livers being discarded, especially right tri-segments. One Committee member noted that it happens often in his region because pediatric programs take all of the blood vessels with the left lateral segment. A Committee member stated that the pediatric programs do this because they do not have any adult candidates for which to allocate the second segment. A Committee member questioned if the variance would actually change such behaviors for pediatric programs.

UNOS staff clarified that the data presented at OPTN regional meetings showed the number of split liver events, not the number of recipients. The number of recipients of a split liver segment would be double the number of split liver events. The data did not contain the number of livers that were reduced or cut-down.

The Committee asked for more clarification on the number and type of splits. UNOS staff presented data from a cohort of patients from 2010 to 2017. According to the data, there were 206 split liver events where the primary split was a left lateral segment in situ and the secondary segment was the right lobe with the middle hepatic vein in situ. There were also 40 split liver events where the primary split was a left lateral segment on the bench and the secondary segment was the right lobe with the middle hepatic vein in situ. In 2018, there were 89 total split liver transplant events. A Committee member asked how many pediatric candidates are on the waitlist and how many get transplanted each year.

The Chair stated that programs wanting to keep the right tri-segment is not new. The concern now is related to broader sharing and not having the variance limited to Region 8. With broader sharing, donors will come from outside of Region 8 and this concerned Committee members. A Committee member asked how a program's ability to keep the right tri-segment would impact their decision to transplant a left lateral segment into a pediatric candidate. The Committee member felt that the liver allocated to a pediatric candidate would be split even if the program is not able to keep the second segment.

A Committee member noted that many fellows do not do splits and some programs will not get up in the middle of the night to do a split. Instead, they do a back table cut-down and the second segment is not used for transplant. A Committee member felt that allowing the program to keep both sides of the liver would not solve this issue. Another Committee member felt that the variance would provide some incentive to not waste the other segment. A Committee member noted that there can also be issues with the vessels of a split liver segment.

A Committee member stated that most pediatric transplants occur at pediatric-only programs and the variance would not change their behavior.

A Committee member stated that the original variance idea was for full left/right splits and it has turned into a debate on pediatric splitting. Another Committee member noted that full left/right splits are different and programs should be able to keep both sides if they do a left/right split.

The Committee member felt that the variance would actually limit sharing of the right tri-segment. A Committee member reminded the group of the requirement to offer the second segment to Status 1 and high MELD candidates within 500 NM of the donor hospital. The Committee member noted that many exception patients would have MELDs below 33, due to Median MELD at Transplant (MMaT) scores. A Committee member stated that any program within the 500 NM circle of a participating program would also want to participate. As such, the Committee member stated that the variance should be open to all programs.

A Committee member asked if it would be possible to require pediatric programs who have accepted an organ to offer out the second segment before bringing the organ back to their center to do an ex vivo split. Another Committee member stated that this would be impossible to mandate.

The Chair asked how the Committee felt about limiting the variance to only full left/right splits. The Committee felt that these splits would not be done frequently.

A Committee member asked about the results of the current open variance. The current variance allows participating programs to keep the left lateral segment if the primary patient receives the right tri-segment. This variance has only been used four times.

A Committee member recommended that the Committee consider a future policy aimed at mandating programs to offer out or use the right tri-segment if the left lateral segment is transplanted into a pediatric candidate. The Committee member felt that too many pediatric candidates are receiving a left lateral segment and the right tri-segment is not being used. UNOS staff stated that they could look at how many partial transplants have occurred. The Chair asked if this data would change the Committee's opinion on the variance being discussed.

A Committee member suggested programs should be sent a letter each time that a candidate is transplanted with a left lateral segment and the right tri-segment is not used for transplant. The letter would ask why the right tri-segment was not used. However, there could be many valid reasons why the right tri-segment was not used.

A Committee member stated that the larger question is how variances will occur under the new allocation system, which does not include regions. The Committee member stated that Region 8 was trying to test an innovative idea but it has become too complicated given the new allocation system. The Committee member was concerned that the new allocation system has the potential to stifle innovation. The Chair suggested that they limit the variance to either full left/right splits or to transplant programs and donor hospitals in Region 8. The Chair noted that the Board and the Executive Committee could change the variance, but it is the role of the Committee to put forth the best proposal possible. A Committee member stated that Region 3 would like to participate in the variance.

The Chair presented the idea to limit the variance to Region 8 for the first 18 months and then open it to any programs for the second 18 months if it were shown to be effective in Region 8. The Chair felt that this could be a reasonable compromise.

The Chair asked if it would be possible from an IT perspective to limit the variance to Region 8. UNOS staff stated that there would not need to be any additional programming for this. Programs in Region 8 would just understand that they would be participating. A Committee member stated that organs from outside of Region 8 would be allocated to programs in Region 8. The Chair clarified that if they were to limit the variance to Region 8, then organs would only come from donor hospitals in Region 8 as well. A Committee member felt that this would be using region as a unit of distribution. A Committee member reiterated that Region 3 would want to participate in the variance. A Committee member felt that regions should still be used for

variances. The Chair agreed that they could recommend using regions for demonstration projects.

A Committee member reminded the group that HRSA has asked the OPTN to do demonstration projects and this is the first time a demonstration project would be done with the new allocation system. Therefore, the Committee's recommendation could set an important precedent.

A Committee member stated that the proposed variance would encourage poor practices such as back-bench splitting and reduced sharing. Another Committee member suggested mandating that livers that meet certain criteria are split.

The Chair stated that they have three options. The first option is the pass the variance as an open variance for any type of split. The second option is to have it be a closed variance, limited to organs procured and allocated in Region 8. And the third option is to limit the variance to only full left/right splits. A Committee member suggested making an open variance for full left/right splits and then a closed variance for Region 8 for any type of split. Another Committee member felt that this would be two different proposals and would not have a large impact.

A Committee member supported opening the variance to any interested program for any type of split. The Committee member felt that if the variance is approved, all programs would want to participate.

Another Committee member asked what would be monitored and how success would be defined. The Chair stated that there is an extensive monitoring plan, but the primary metrics to be tracked are the number of splits and the demographic information of who receives the splits. The Chair noted that monitoring the variance will be more difficult if it is an open variance and any program can participate.

One of the Committee members was surprised that many of the regions did not support the proposal and did not think that the Committee should recommend the proposal when it received such mixed support. The Committee asked if it would be possible to recommend an open variance, but if that is not approved by the Board, then limit the variance to Region 8. UNOS staff stated that if the Committee decided to put forth a primary and secondary recommendation, they would need to vote on the policy language for both proposals.

A Committee member put forth a motion to vote on the proposed variance as it was written for public comment. The motion was seconded. The Chair reminded the Committee that they needed to decide if they want the variance to be open or closed. The public comment proposal was for an open variance. UNOS staff clarified that the policy language presented to the Committee was updated from the public comment document. The substance of the policy is the same, but the language was made clearer.

A formal vote was taken on: do you support an open variance for all types of split livers, as written in the public comment proposal?

Results were as follows: Yes 10 (59%); No 5 (29%); Abstain 2 (12%)

The Chair then asked if the Committee would like to have a back-up proposal in case the first proposal is not approved by the Board. One Committee member suggested that the back-up should be a closed variance limited to Region 8. The Committee was concerned that the mixed support for the variance in public comment may cause the Board to vote against the Committee's recommendation, even though the Board previously supported having an open variance. A Committee member stated that it does not make sense to have two opposite recommendations on the same proposal. The Board can, ultimately, choose whichever option they want, so the Committee should only send what they think is the best recommendation. However, it would be reasonable to vote on the full left/right split option, because it is a different

aspect of the variance than open/closed. One region supported limiting the variance to left/right splits because they thought the proposed variance was unfair to programs that don't have a pediatric component. However, the open variance for any type of split would include full left/right splits.

One Committee member clarified that full left/right splits do not need to be between two adult candidates, and a segment could be transplanted into a pediatric candidate. The Committee member also suggested that if the Committee recommends a back-up variance for full left/right splits only, it should not include the requirement to share the second segment to 500 NM. A Committee member reiterated his or her support for limiting the variance to full left/right splits because the proposed variance could disadvantage programs without a pediatric component.

The Chair noted the Committee's primary recommendation as voted on above, but also stated that she could offer amendments to the proposal if the Board did not approve the primary recommendation. The first amendment would be to limit the variance to Region 8 and the second would be to limit the variance to only left/right splits. She would only offer these amendments if the primary recommendation is not approved.

A Committee member stated that the recipient of the primary offer for a full left/right split will not be advantaged by the proposed variance. A full left/right split may be suitable for large pediatric or small adult candidates, but it may not be ideal for full-size, high MELD adults to receive a hemiliver split.

A Committee member asked how the Chair will say that the Committee incorporated the public comment feedback if asked at the Board. The Chair stated that she will need to address specific comments and make it clear that the proposed variance is time-limited and will be closely monitored.

A Committee member asked how success will be defined for the variance. The Chair stated that the monitoring plan includes a number of different metrics that will be tracked, but it is ultimately up to the Committee to decide if the effect of the variance on the end points constitutes success. UNOS staff highlighted a few of the metrics that will be tracked as part of the monitoring plan. The following metrics (among others) will be tracked as part of the monitoring plan:

- Number of split liver transplants
- Characteristics of split liver recipients
- Liver discards
- If the remaining segment stayed at the same or an affiliated program
- Geography of the secondary recipient as it relates to index recipient
- The number of programs performing split livers transplants and participating in the variance

The Chair suggested monitoring outcomes by geography as well. UNOS staff noted that they might be able to compare outcomes at programs that are participating in the variance versus programs that are not participating in the variance. They will need to track who is participating, and based on that, the evaluation of the variance could be between participating and non-participating programs or it could be for the entire nation. A Committee member suggested tracking the number of pediatric exception requests for Status 1B at participating programs to make sure they are not inflating pediatric scores to receive more liver offers. Another Committee member suggested tracking the number of split livers versus cut-downs. UNOS staff presented data on the number of split liver transplants by OPTN region.

A Committee member noted that there may be confusion about what it means to enter a "partial" transplant in UNet^{SM}. Entering that a partial transplant was done means that it was a cut-down

of a liver, not one of the segments of a split liver. The Committee member noted that there may need to be community education on this distinction. UNOS staff agreed that there could be confusion about this. For example, if a liver is split but the second segment is not transplanted, it may be recorded as a split liver, but it should be considered a partial transplant. The Committee agreed that this is a confusing, but important, distinction.

The Chair asked the Committee if there was anything else that should be monitored. They do not need to define success at this time, but they do need to make sure that they track all of the metrics they need. UNOS staff stated that monitoring reports will be produced at 6 months, one year, two years, and three years after implementation. If there is anything not captured in the first report, it could be added to subsequent reports.

A Committee member asked how "affiliated program" is defined. UNOS staff stated that programs interested in the variance will need to state their affiliated program in the application. A Committee member felt that it should be clarified that the affiliation must be between one adult and one pediatric program, not two adult programs. Another Committee member asked if two programs that are geographically distant could affiliate.

UNOS staff noted that they avoid using "transplant center" in policy because it could refer to any transplant program at the center. Therefore, policy uses the term "transplant program" which is more specific. There is no definition in policy for "affiliation." In previous variances, affiliation was self-defined by participating programs. The Chair asked who will adjudicate the self-declared affiliations. The Chair noted that some institutions have a number of programs across the country, such as the Mayo Clinic and the Cleveland Clinic. A Committee member suggested mandating that the two affiliated programs must be within 500 NM of each other. A Committee member noted that some surgeons are on staff at two different transplant programs, which might be considered an affiliation. A Committee member stated that if the variance is limited to full left/right splits then this would not be as much of an issue.

The Chair stated that it is very rare to have a surgeon on staff at two programs, but it is more common to have two adult programs that are affiliated. The Chair suggested requiring one of the two programs to be a pediatric program. The Committee agreed that adding this requirement to the policy language was a good idea.

UNOS staff presented the updated variance language with the additional requirement that one of the two affiliated programs must have an active pediatric component and that participating programs must identify their affiliated program in their application.

A Committee member asked if pediatric programs would only be limited to one affiliation. The Committee agreed that pediatric programs should only be allowed to affiliate with one adult program so that pediatric programs do not have multiple affiliations. The Chair noted that very few pediatric programs are not already affiliated with an adult program. The Chair also clarified that each program does not need an affiliated program in order to participate. UNOS staff asked if both affiliated programs must submit applications for the variance or just one. The Chair stated that both programs would need to apply. A Committee member asked if two adult programs would be allowed to affiliate to do full left/right splits. The Chair stated that this is not likely.

A Committee member asked who will review the applications. UNOS staff stated that, in the past, the applications have been reviewed by UNOS staff and any questions would be brought to the full Committee. Another Committee member noted that requiring one of the affiliated programs to be a pediatric program would be beneficial because it would decrease discards at the pediatric program. A Committee member was concerned that allowing programs to affiliate just for the purposes of this variance would cause less sharing and encourage poor practices.

The Committee agreed that each program can only affiliate with one other program and one program must have a pediatric component.

A formal vote was taken on: do you support the updated variance language?

Results were as follows: Yes 10 (59%); No 5 (29%); Abstain 2 (12%)

Next Steps:

UNOS staff will incorporate the Committee discussion and vote into a briefing paper to be presented at the June 2019 Board meeting.

6. Service Recognition and Incoming Roster

The Chair recognized those Committee members whose terms are ending in June. The Chair expressed gratitude to all Committee members for their dedication during this difficult time. The Chair presented the incoming Committee members. UNOS staff and Committee members recognized the Chair for her work and dedication.

Next Steps:

No next steps were identified.

7. Existing Split Liver Variance

There is an existing open variance for segmental liver transplantation. The variance has only been used approximately four times. The Committee needed to decide whether to recommend to the Board to end the old variance or not.

Summary of Discussion:

Under the old variance, if a program transplants a right lobe or right tri-segment into the primary candidate, the program is able to offer the left lobe or left lateral segment into a different candidate at the same program or an affiliated pediatric program. The variance was going to be evaluated after the first ten transplants, but there have only been four transplants so far. A Committee member stated that this variance was not used often because Share-35 allocated more livers to high MELD candidates, and these candidates are not good recipients of split livers.

A Committee member stated that his or her program has done this type of split many times, but it has not been under the variance. UNOS staff noted that there could be more instances where the right lobe or tri-segment is transplanted into the primary candidate and the second segment is allocated to another candidate at the same or an affiliated institution, but there have only been four instances where the variance was used at participating programs. Policy also allows the transplanting program to keep the second segment if it is not placed by the time that the procurement team goes to the OR. Therefore, some programs may have been able to keep the second segment, but it was not a result of this variance. Currently, only Region 2 and four other OPOs participate in the variance.

One Committee member stated that this variance has been around since 2005 and, at this point, it should either become policy or be shut down. The Chair stated that the variance is clearly not working as intended. Additionally, the new variance encompasses this variance so there is no reason for programs to participate in the old variance any more. A Committee member felt that they should not recommend that this variance be ended until the Board approves the new variance. UNOS staff asked what will be accomplished with the old variance if it is kept active. The Chair asked if it would be possible to discuss the variance with OPOs to see if they are using it and not reporting it. The Committee supported keeping the variance until the new variance is approved by the Board and they get more information on how often it was

actually used. A Committee member noted that this variance will not be used if the new variance is approved.

A Committee member stated that the best way to increase splitting would be to define criteria for livers that are required to be split. Livers that meet the criteria would only be offered to programs that would split them. Other Committee members noted that this would increase discards and many programs are not comfortable splitting livers.

Next Steps:

The Committee recommended keeping the variance open and active until the Board votes on the new variance and they get more information on how often the old variance was actually used.

8. NLRB and Acuity Circles Evaluation Plan

The National Liver Review Board (NLRB) and AC distribution system are slated to be implemented on April 30, 2019.[1] UNOS staff presented details of the evaluation plan for these two policy changes, as well as the ABO variance.

Summary of Discussion:

The Chair stated that it is important for the Committee to understand the monitoring plans for the upcoming policy implementations so that they can propose changes to the policy in the event of any negative outcomes.

UNOS staff presented the evaluation plan for the NLRB first. The six-month data report will include the total number of exception cases, broken down by those that met policy criteria and were automatically approved and those approved by the NLRB. It will show data on the exception scores of candidates who were transplanted. The report will also show waitlist dropout rates for exception and non-exception candidates, as well as candidates who were denied an initial exception. There will be a one-month data report, but it will not be as in-depth as there will not be much data. UNOS staff asked if the Committee preferred to have the six-month data report six months after implementation with four months of data, or seven to eight months after implementation but with six months of data. The Committee preferred having six full months of data in the report.

The one-month report will be presented at the July 2019 Committee meeting and will include information on the number of forms stratified across different classifications, outcomes of the forms, and details on forms that were not automatically approved.

A Committee member suggested adding the number of forms where the transplant program requested a score other than the policy assigned score and whether or not the requested score was granted. The Committee member wanted this to be tracked for both standard and non-standard diagnoses. The Committee member also suggested adding the number of exception scores requested and whether they are approved or not by region. This will be helpful in understanding how the NLRB functions in relation to previous regional review boards (RRBs). The Committee member also requested that there be analysis showing if an exception patient would have been transplanted in the previous RRB model versus the NLRB. Another Committee member stated that they should examine if candidates with the same condition are being assigned different scores. Another Committee member noted that this will happen in the NLRB so it is more important to look at time on the waitlist to see if the candidates have the same opportunity for transplant. A Committee member noted that waiting times will change as MMaT

---

[1] The implementation date has since been changed due to pending litigation.

scores equalize across the country. Another Committee member noted that due to demographic differences, there will always be differences in MMaT. A Committee member stated that regional MMaTs are already fairly similar, but there are large differences in the number of donors in each region. Another Committee member suggested looking at days on the waitlist with an exception by region and by diagnosis because time on the waitlist with an exception will become more important under the NLRB. Another Committee member stated that time on the waitlist is not as important as waitlist mortality or dropout.

A Committee member was concerned that the increased importance of time on the waitlist with an exception could benefit the wrong candidates. In the current system, hepatocellular carcinoma (HCC) patients move up the MELD elevator to gain priority, but they are de-prioritized relative to non-exception patients in the new system. The Committee member felt that HCC patients would benefit the most, but they are disadvantaged in the NLRB system. The Committee member wanted to track this if possible. The Chair stated that this happens in the current system already. A Committee member stated that transplant programs are good at managing their own list so there should be a way for doctors to use clinical judgement to rank their own patients. The Chair noted that this would impact candidates listed at other programs in the same unit of allocation. The Chair suggested looking at this issue again after the NLRB is implemented and they have a chance to review the data.

A Committee member proposed looking at the number and rate of offers and declines for exception and non-exception candidates. Another Committee member commented that these metrics should be stratified by days with an exception. A Committee member stated that HCC candidates in high MMaT areas will be transplanted above lab MELD candidates in low MMaT areas. Another Committee member stated that HCC candidates were previously over-advantaged so the new system should function appropriately. However, the areas with high MMaT will benefit until the MMaT scores equalize.

The Chair stated that they will be monitoring the NLRB as soon as it is implemented and can propose changes to the system if anything drastic is occurring. However, it will be difficult to understand the true effects of the NLRB until the six-month report. Another Committee member noted that it will take time for MMaT scores to equalize, so they should not make any changes until this occurs.

A Committee member asked who is going to review the performance of the review board members. The OPTN will be monitoring when reviewers do not submit their votes on time and the number of times that a decision is appealed. A Committee member commented that if there are reviewers that are too lenient or too strict, then there should be a way to identify and re-educate them. The Chair suggested periodically sending out test forms to reviewers, and then measuring their responses to these forms. However, because it is a random group of five reviewers for each form, it will be difficult to compare one reviewer's performance to another's. The Chair then recommended that they should monitor the number of times that each reviewer is in the super majority. The Committee agreed that this was a good idea.

A Committee member commented that they should monitor how often each reviewer voted in accordance with the guidance document. However, another Committee member noted that the guidance document allows room for individual judgement, otherwise all scores could be automatically approved. UNOS staff noted that the reviews will have to be aggregated so that individual reviewers cannot be identified. A Committee member commented that there should be a final reviewer or editor that can review the performance of all the review board members. The Chair stated that this is the function of the NLRB Chair.

The one-month NLRB data report will also include information on the amount of time it takes to adjudicate cases and the number of appeals to the Appeals Review Team (ART). A Committee member asked if programs will know what the vote on their exception form was or if they will only know if it was accepted or rejected. The Chair stated that NLRB members will need to enter the reason why an exception was denied so that the program can address the concerns if they choose to appeal. And, the votes will be provided to the program once the vote is resolved. The NLRB Chair commented that UNOS staff are able to tell when there are obvious cases so that they can see when a reviewer is consistently voting against the super majority. The NLRB Chair also noted that timeliness is important so they should monitor if reviewers are submitting their votes on time. The NLRB Chair will monitor this and reach out to reviewers who are not performing well.

A Committee member reiterated that they could measure performance relative to the guidance document. The Committee member felt that reviewers do not need to follow the guidance document every time but if they are not following it for a majority of cases, then that should be addressed.

Another Committee member commented that they should continue to review and update the guidance document. The Chair suggested sending an annual survey to NLRB members asking about the guidance document and the system to make sure that it is performing optimally.

A Committee member stated that it would be useful to have information on forms by diagnosis. UNOS is working on a project to look at key words in exception forms to see if there is a correlation with exception scores. The Committee could leverage this machine-learning technology in the future.

A Committee member recommended looking at exception scores by gender because females are disadvantaged in getting an exception score. Another Committee member noted that the forms may not include gender unless it is mentioned in the narrative. A Committee member stated that it is more important to understand why women are not getting the same opportunity as men. The Chair stated that women have a higher waitlist mortality and lower transplant rate and the reasons have been documented in the medical literature. The Committee member still felt that they should monitor if there is a difference in approval of exception scores for women as compared to men. Another Committee member stated that the way to reduce the disadvantage for female candidates is to give them an extra MELD point.

UNOS staff then presented the monitoring plan for the AC distribution policy. A Committee member suggested tracking deceased donor transplants by OPO and comparing the number of actual transplants to the number of excepted transplants. The Committee member also recommended breaking down the waitlist into exception vs non-exception candidates, and the number of candidates with a MELD or PELD greater than 15. The Committee member asked which geographic areas will be used when monitoring variance in MMaT. UNOS staff stated that MMaT variance will be calculated by local, region, and nation, as well as the different circles of allocation. UNOS staff also stated that they will look at the effect of the new allocation system on individual transplant programs, especially within the first few months after implementation. A Committee member requested that the graphic depicting the percent of deceased donor transplants by recipient characteristics be stratified by region. UNOS staff stated that the first report will not have data broken down by OPO because the numbers would be small. A Committee member commented that transplant rate can be misleading because it is largely dependent on the size of the program's list. Another Committee member suggested that transplant rate be broken down into different MELD groupings. Under the previous allocation system, pediatric donor organs often went to adult candidates, so they will monitor the recipient age group of pediatric organs.

UNOS staff will monitor the distance between donor and recipient hospitals and cold ischemic time. The Chair asked if they could use distance between donor and recipient hospital as a proxy for transportation type. For example, the Chair asked if they could consider any organ that travelled more than 150 NM as a flown organ, and anything less than 150 NM as having been driven. Another Committee member stated that transportation method should be tracked in UNet[SM]. The Operation and Safety Committee recommended collecting this data, as well. And, the Acuity Circles Subcommittee (AC Subcommittee) is also discussing this topic. The Chair suggested adding a field in UNet[SM] to be completed when removing a candidate from Waitlist[SM] that tracks if the organ was flown or driven. In the meantime, the Chair asked if they could consider any organ that travelled more than a certain distance as having flown. A similar method was used to calculate the percent of organs flown in the Scientific Registry of Transplant Recipients (SRTR) modelling for AC, and the Chair recommended using the same methodology in the monitoring plan.

The monitoring report will also include information on the time between first electronic offer and cross-clamp. This is important data as it shows the time it takes to get to the OR. The report will also include discard rate, as utilization rates are typically high. Another Committee member suggested tracking discarded organs in the OR and if they get placed locally. The Chair noted that this is part of the issue of late reallocations. The Chair stated that a field tracking late reallocations should be added to UNet and OPOs should enter this information. UNOS staff noted that adding this field was part of the expedited liver placement proposal from the OPO Committee. The Chair stated that this project could take an extended period of time to implement, so the Committee should still move forward with trying to add this field in UNet.

A Committee member suggested monitoring acceptance and subsequent declines of liver offers. The concern is that programs will accept an organ and then decline the offer as better organs become available. This could happen multiple times for an organ, which would then become difficult to place.

SRTR staff noted that in the liver simulated allocation model (LSAM) modelling for AC, flying versus driving for an organ was based on Google travel distances, not a set distance between the donor hospital and transplant program. The distance used as the threshold for flying versus driving was two hours driving. If the distance between the donor hospital and transplant program was more than two hours driving, then the model considered the organ to be flown.

UNOS staff noted that the six-month report will include more information on transplant rates and outcomes because there will be more data. The Chair noted that OPOs do not always keep track of the transportation method used, so it is crucial to add a data collection field in UNet. UNOS staff reminded the Committee that this would need to go through Office of Management and Budget (OMB) for approval and that the Operations and Safety Committee is working to add a similar field.

<u>Next Steps:</u>

UNOS staff will incorporate the Committee's feedback in the monitoring reports. The Liver Committee feedback will also be shared with the Operations and Safety Committee.

9. Sub-Committee/Workgroup Reports

The Committee currently has the AC Subcommittee that is focused on anticipating logistical challenges in AC distribution and proposing solutions to any potential challenges. The Committee also has the Hawaii/Puerto Rico Workgroup (HI/PR Workgroup) that is dedicated to improving access to transplantation in Hawaii and Puerto Rico.

Summary of Discussion:

The HI/PR workgroup has not met yet, but they will be discussing ways to increase access for Status 1 candidates in Hawaii and Puerto Rico under AC. In the previous allocation system, Status 1 candidates in Hawaii and Puerto Rico had access to regional shares from Regions 6 and 3, respectively. However, there are no more regional shares in AC. This issue was brought to the attention of the Committee during public comment and is a concern of the programs in Hawaii and Puerto Rico. The HI/PR Subcommittee will have a proposal for the full Committee soon, as they anticipate a public comment proposal in the fall.

The AC Subcommittee has come up with a number of ideas to improve the AC distribution system. The first problem identified by the Subcommittee was late declines of livers and lack of definition for when the program must enter a final acceptance. This currently happens, but may happen more frequently with broader sharing. The issue is when a program accepts two livers for the same patient, goes to the OR and recovers the first liver, and then brings the first liver back to their own center for final review before releasing the second liver. This delays going to the OR for the second liver. It is also a problematic practice for a program to bring a liver back to their program (even if they have not accepted a second liver) and then decline the liver because of size. The AC Subcommittee proposed that each liver must be accepted with intent to transplant within one hour of cross-clamp. The program can only decline the offer after that if the intended recipient dies or is found to have an unexpected problem. This would release the second accepted liver and should reduce late reallocations.

One Committee member suggested that if a program leaves the OR with an organ, then all other accepted offers should be released for reallocation. A Committee member noted that if a program accepts an organ from waivers, then the program should be able to keep the second liver past one hour. Other Committee members felt that it was important to retain the ability to accept another liver if a better, more suitable organ becomes available. The Chair stated that once an offer is declined, then the candidate would still be eligible to receive other offers.

A Committee member noted that some programs bring a liver back to their program and then decline for size and they then try to use the organ in another candidate at their program, bypassing the match run. The proposed solution would likely reduce this behavior. A Committee member commented that Region 1 had a similar rule, but with the added stipulation that the organ must be accepted within one hour at the donor hospital.

A Committee member stated that only being able to accept two livers for each patient is already restrictive enough and any more restrictions could harm the sickest patients. The Committee member suggested exempting Status 1 candidates from the proposed policy.

The Chair stated that there is not currently a way to track late declines, but the Committee is working with the OPO Committee to add this data to UNet. A former Committee member noted that some OPOs are already tracking late declines. If OPOs agree to monitor this, it may not need to be a field that is added to UNet and would therefore not need to go through the OMB approval process. The Chair stated that the Committee could not require OPOs to do this. The former Committee member stated that by monitoring late declines in Region 5, they were able to cut-down on the behavior. The former Committee member suggested that having OPOs monitor late declines could be an effective way to reduce the behavior until a policy is implemented or data field added to UNet.

A Committee member noted that the proposed solution would cause more livers to be allocated through expedited placement, and the procurement team already in the OR would have the best opportunity to get the organ through expedited placement.

A Committee member commented that the proposed solution could delay cross-clamp, which would impact other organ procurement teams and cause other logistical issues. A Committee member noted that most programs can decided well within an hour if they can use the liver. Another Committee member stated that his or her program does not procure a large portion of the livers transplanted at his or her program. Therefore, they need to bring the liver back to their center before final acceptance. Another Committee member suggested that the proposed solution not apply to Status 1 candidates. The Committee member noted that programs accept marginal offers for highly urgent candidates, and they should still be able to accept a better offer if one comes along. The programs and the candidates should not be disadvantaged for being willing to accept marginal livers.

The AC Subcommittee will consider this feedback and continue to discuss the issue during their next meeting.

Another issue discussed by the AC Subcommittee was the unwillingness of liver procurement teams to recover other abdominal organs. The Subcommittee proposed setting a requirement that if there is no local team present for the procurement that wants to recover the other abdominal organs, the team recovering the liver will recover any other abdominal organs intended for transplant. Committee members agreed that there is variation in the willingness of liver procurement teams to also recover the other abdominal organs. One Committee member noted that if it is a donation after circulatory death (DCD) donor, they do try to transplant the organ as quickly as possible. A Committee member stated that it is important to define what "recover" means because the liver team should not be responsible for the biopsy, packaging, and labeling of the organs. A Committee member noted that some fellows do not have the ability procure pancreata. The Committee agreed that pancreata should not be included in the requirement.

The Committee agreed that this should move forward as a policy proposal.

The AC Subcommittee also discussed the fact that the time to get to the OR for marginal donor livers may be prolonged as patients with high MELD scores will accept a marginal liver and plans will be made to go to the OR but then the program will get a better offer for the same patient and subsequently decline the marginal liver. This could happen multiple times for a marginal liver. The Subcommittee recommended monitoring the time to placement of non-DCD, abdominal-organ-only donors before and after AC is implemented. If the time to placement is prolonged, then the AC Subcommittee will consider different solutions. A Committee member stated that OPOs will have to be part of the solution to this issue.

The AC Subcommittee is also considering drafting a guidance document to make it easier for organ recovery by local teams. One of the concerns with AC is the potential for increased costs, travel, and logistical complexity. Having more local recovery could reduce some of these concerns. The AC Subcommittee felt that the lack of standard intra-operative imaging and procurement techniques may be impairing the willingness of programs to allow for local recovery. The AC Subcommittee felt that creating a guidance document about standard procurement techniques and information sharing could allow for more local recovery, and therefore reduce costs, travel, and logistics. The AC Subcommittee is also considering creating a survey to inform the drafting of the guidance document.

The AC Subcommittee is also generating a list of what data need to be tracked before and after AC implementation in order to monitor changes in costs as a result of AC.

<u>Next Steps:</u>

The AC Subcommittee will consider the Committee's feedback and move forward with the policy development process accordingly.

10. Open Session

Summary of Discussion

The Chair noted that some members of the transplant community have new ideas on liver allocation. Specifically, one idea related to how HCC candidates are ordered on the match run. The idea was to use data on HCC to order the candidates instead of exception scores. Two groups have developed different systems to do this and both are interested in talking to the Committee in the future. One of the groups is concerned that using MMaT-3 for HCC candidates assigns too low of a score to HCC candidates.

The Chair noted that women are disadvantaged by the MELD calculation and stated that the Committee could consider adding one MELD point for female candidates as a future project. The Chair also mentioned that the pediatric end-stage liver disease (PELD) calculation does not accurately reflect disease severity of pediatric candidates, so the Committee could consider altering the PELD formula as a future project.

A Committee member stated that the American Society for Transplant Surgeons (ASTS) is exploring ways to compensate surgeons for procuring organs for other transplant programs. The Committee members should stay informed of this conversation. Compensation for procurement for other programs varies across the nation.

Another Committee member stated that the Committee should closely monitor AC to see if organs are actually going to the sickest patients first. If organs are not being allocated to the sickest patients first, the Committee member recommended continuing to revise allocation policy until they are allocated to the sickest first. The Committee member stated that organs should be going to those candidates who are closest to dying, even if their MELD score does not reflect this severity.

A Committee member noted that there are many programs transplanting candidates with acute alcohol hepatitis and the transplant community must figure out how to best prioritize and care for these patients. One suggestion was to have programs create a protocol to show that they have the ability to care for these patients, similar to cholangiocarcinoma. For acute alcohol hepatitis, this would make programs have a plan in place to mitigate and monitor recidivism. The Committee member felt that this could be a project for the Committee in the future. The Committee member noted that the Committee may want to consider how to responsibly prioritize and treat these patients.

Another Committee member proposed assigning these candidates a set MELD score and then having the MELD score increase if the candidate is able to stay sober while on the waitlist. Other Committee members thought that these patients were too sick to have such a MELD elevator. A Committee member asked if it would be possible to assign these candidates a MELD score below their calculated MELD. The Committee noted that it is not clear how many candidates on the waitlist have acute alcohol hepatitis. Many of the alcohol hepatitis candidates are coded as having alcohol cirrhosis because insurance companies often do not cover treatment for alcohol hepatitis. However, the number of patients with alcohol hepatitis is growing. Furthermore, it is unclear how these patients should be treated and when transplant becomes the best treatment option. A Committee member stated that there should be better guidelines on how to treat these patients. Another Committee member commented that the OPTN has the regulatory authority to establish guidelines and monitor outcomes for these patients.

Another Committee member noted that there should be some criteria for listing alcohol hepatitis candidates, but they should not have their MELD scores changed because of their medical condition. A Committee member stated that there should be a more standardized data collection

process for alcohol hepatitis patients. A consensus conference is working on creating a definition of alcohol hepatitis. Another Committee member reiterated that having programs submit a protocol to treat these patients, similar to cholangiocarcinoma, would be a good solution. A Committee member felt that transplant programs would embrace more guidance on how to treat these patients.

Next Steps:

UNOS staff will document the new project ideas and the Committee will prioritize their work at a future meeting.

Upcoming Meeting

- May 9, 2019 - Teleconference