OPTN Liver and Intestinal Organ Transplantation Committee
Meeting Summary
October 11, 2022
Chicago, IL

James Pomposelli, MD, PhD, Chair
Scott Biggins, MD, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via in Chicago, IL and via Citrix GoToMeeting teleconference on 10/11/2022 to discuss the following agenda items:

1. Public Comment Review and Vote: Review of Liver and Intestine Variances in OPTN Policy
2. Public Comment Review and Vote: Continued Review of National Liver Review Board (NLRB) Guidance
3. Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B Implementation Clarifications
4. Continuous Distribution Attribute: Optimized Prediction of Mortality (OPOM)
5. Continuous Distribution Attribute: Supply/Demand
6. Continuous Distribution Attribute: Donor Factors
7. Continuous Distribution Re-cap Presentations
8. Attribute Benefit versus Feasibility

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

1. Public Comment Review and Vote: Review of Liver and Intestine Variances in OPTN Policy

The Committee reviewed public comments from the transplant community regarding the *Review of Liver and Intestine Variances in OPTN Policy* proposal.

Summary of discussion:

Feedback from the transplant community during public comment was supportive of the proposal. The Committee did not make any post-public comment changes.

The Committee unanimously supported sending the *Review of Liver and Intestine Variances in OPTN Policy* proposal to the OPTN Board of Directors for consideration.

Next steps:

The OPTN Executive Committee will consider this proposal during the October 26, 2022 meeting.

2. Public Comment Review and Vote: Continued Review of National Liver Review Board (NLRB) Guidance

The Committee reviewed public comments from the transplant community regarding the *Continued Review of National Liver Review Board (NLRB) Guidance* proposal.

Summary of discussion:

Feedback from the transplant community during public comment was supportive of the proposed guidance. Based on specific suggestions provided during public comment, the Committee proposed the following changes post-public comment:

- Added language to clarify that the cystic fibrosis guidance applies to liver-only candidates

These post-public comment changes were reviewed and supported by pediatric cystic fibrosis subject matter experts.

A member noted that the guidance will need to be monitored to ensure there is not a surge of hepatic adenoma transplants. Another member agreed and noted concern that the drafted guidance suggests priority for transplant for pre-malignant lesions. Another member responded that the previous guidance required candidates to demonstrate malignancy, which then results in the candidate being outside of the criteria resulting in less access to transplant. The member stated the proposed guidance intends to create a pathway where hepatic adenoma candidates have access to transplant based on consistent guidance.

A member asked how frequently beta catenin positive lesions turn into a malignancy. Another member responded that there is literature, but noted there are additional indications, such as hemorrhaging. The member added that the guardrails in the guidance are that it is unresectable.

A member suggested to modify the NLRB guidance language to add additional context to the unresectable adenoma criteria. Another member suggested adding more specification to the term "medical management" in the hepatic adenoma guidance. A member responded that it may be more beneficial to leave the guidance with broad language. Members agreed and stated that the guidance related to hepatic adenoma will need to be monitored.

The Committee unanimously supported sending the *Continued Review of NLRB Guidance* proposal to the OPTN Board of Directors for consideration.

Next steps:

The OPTN Board of Directors will consider this proposal during the December 5, 2022 meeting.

3. *Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B* Implementation Clarifications

The Committee reviewed clarifications and implementation procedures related to the recently OPTN Board of Directors approved *Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B* proposal[1].

Summary of discussion:

The OPTN Executive Committee will consider the following clarifications as they relate to the implementation of the *Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B* proposal:

- Institute transition periods for laboratory value updates upon implementation (same procedure as MELD Sodium (MELD-Na) implementation)
- Simplify data collection for "current sex"
- Remove "Bilirubin PSC/PBC/Other Cholestatic" data element

Next steps:

The Committee will submit a mini-brief outlining the above clarifications to OPTN Executive Committee for consideration[2].

[1] OPTN Liver & Intestinal Organ Transplantation Committee, *Briefing Paper,* Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B. Public Comment January 27, 2022 – March 27, 2022. Available at https://optn.transplant.hrsa.gov/.
[2] OPTN Liver & Intestinal Organ Transplantation Committee, *Mini-Brief,* Transition Periods for Recertification of Liver Laboratory Values and Other Technical Corrections. October 26, 2022 OPTN Executive Meeting.

4. Continuous Distribution Attribute: Optimized Prediction of Mortality (OPOM)

The Committee discussed Optimized Prediction of Mortality (OPOM) as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

The researchers who developed OPOM presented their work to the Committee for consideration. The presentation included the following information:

- OPOM was developed utilizing machine learning Optimal Classification Tree models[3]
- Predictive accuracy of OPOM vs model for end stage liver disease (MELD) for all candidate groups with increasing disease severity
- Liver simulated allocation model (LSAM) used to compare OPOM to MELD-based allocation on effect on hepatocellular carcinoma (HCC) vs non-HCC candidates, and effects on gender inequity
- OPOM does not use an explicit formula or calculation, but rather uses a series of questions to arrive at the prediction of waitlist mortality
    - There may be up to ten sequential questions (i.e. variables) that need to be answered before the model arrives at a waitlist mortality prediction
    - The questions (i.e. variables) and corresponding thresholds that are being used to split at each node were determined by the model in order to maximize the predictive performance
- The model utilizes 28 variables
    - Data for each variable is currently collected by the OPTN and was retrieved from OPTN STAR files
    - 20 of the variables are associated with the traditional MELD, but in this model are applied with the use of trends (e.g. difference in creatinine levels since previous test)
    - For HCC candidates, the model includes variables related to alpha fetoprotein (AFP), tumor number, and tumor size
    - The model currently utilizes age as a variable however, age can be omitted as a variable without any loss in predictive performance
- Current data limitations include:
    - Area under curve (AUC) calculations using data up to 2016
    - LSAM results using organ procurement organization (OPO)-based allocation and 2010 cohort
- OPOM maintains predictive accuracy for the sickest transplant candidates
- OPOM maintains predictive accuracy across sex, allocates more organs to female transplant candidates, and leads to substantial mortality reduction for both sexes
- Limitations of OPOM
    - OPOM is more complex than MELD
    - OPOM does not account for non-HCC exception candidates
    - LSAM does not account for transplant program or practitioner behavioral changes
- OPOM objectively and more accurately prioritizes HCC and non-HCC candidates for liver transplantation based on disease severity
- In simulation, OPOM results in a significant number of additional lives saved every year, and higher rates of transplant for non-HCC and female candidates

[3] Bertsimas D, Dunn J. Optimal classification trees. Mach Learn. 2017;106:1039-1082

- Independent validation of OPOM by Toronto group (ATC 2019)
- These data demonstrate the potential of machine learning technology
- Ongoing analysis
    - AUC, LSAM calculations using more recent data
    - OPOM with female point offset to study how mortality reduction gains are split across sexes
    - OPOM using MELD 3.0 as a variable
    - Tradeoff analyses similar to the work with the OPTN Lung and Kidney Transplantation Committees
- Summary
    - To include HCC stratification, HCC candidates interdigitating with non-HCC and increase accuracy of medical acuity is possible by adopting OPOM.
    - OPOM is easy to understand and can be refitted regularly to maintain high accuracy
    - OPOM ameliorates both gender disparity and disparity between HCC and non-HCC candidates
    - OPOM will likely save many more lives than previous changes in organ distribution
    - OPOM can include any social determinants of health variables that are collected (now and in the future) if they are predictors for waitlist mortality
    - The Committee may consider using the most accurate model for medical acuity attribute that includes solutions for problems that have been well characterized by the subcommittees

The Chair asked whether the use of MELD 3.0 in OPOM will overcorrect the sex disparity. A member of the community stated that may occur. The Chair asked whether OPOM will readjust if an overcorrection is seen. The member of the community stated that it depends on what variables are utilized. The member of the community stated that sex is not currently a variable in OPOM. The member of the community stated the sex disparity evened out with OPOM due to the model being a more accurate prediction of waitlist mortality.

The Chair asked how often OPOM recalculates. The member of the community stated that it depends on the clinical changes of the candidate. The member of the community stated that updated laboratory values for a candidate may result in a new OPOM score. The member of the community stated that the variable cut offs and the order of the branches are determined by the computer. The member of the community explained that OPOM could be readjusted at any point with a new data set to continually improve the accuracy.

A member asked how age is utilized in OPOM. The member of the community stated that age was omitted as a variable with minimal impact to the model's waitlist mortality predictions. The member of the community stated it would be the Committee's decision whether or not to include age as a variable in OPOM.

Another member asked whether OPOM incorporates disease etiology. The member of the community stated that disease etiology is a variable in OPOM. The member of the community added that sub-analyses could be performed on certain populations and OPOM to determine relative advantages or disadvantages.

The Chair of the OPTN Pediatric Transplantation Committee asked how the pediatric population is incorporated into OPOM. A member of the community stated that models for pediatrics have been developed but due to the small numbers in the pediatric population, there was not a statistically significant difference observed in the simulations. The member of the community explained that the

analyses could be extended to the pediatric population but due to the small size there has not been a demonstrated significant advantage.

Another member asked for more information on how OPOM interdigitates HCC candidates. The member stated that HCC criteria are occasionally updated and wondered how that is incorporated into OPOM. Another member of the community responded that every HCC candidate would have a different score under OPOM, because OPOM combines lab MELD scores, AFP, number of tumors, and size of tumors. The member of the community that it has yet to be determined how to address non-HCC exception candidates in OPOM.

A member noted that models are only as good as the input data. The member noted that data quality tends to improve over time due to more attention and corrective feedback loops. The member asked whether the model will change if it utilizes data subsequent to 2016. The member of the community agreed that the model is dependent on the quality of data collected by transplant programs. The member of the community stated that laboratory values tend to be more accurate than other data measures such as functional status. The member of the community noted that most of the variables used in OPOM would be easy to verify via electronic medical records.

Another member asked if OPOM will be impacted by sicker transplant candidates who have more laboratory measurements performed. The member asked if OPOM prioritizes transplant candidates with chronic kidney disease. The member of the community stated that creatinine and change in creatinine are both important variables in OPOM. The member of the community stated that the purpose of OPOM is to predict mortality on the waitlist. The member asked whether post-transplant outcomes have been analyzed based on OPOM score. The member of the community stated that post-transplant outcomes have not been analyzed based on OPOM score.

The Vice Chair noted that the liver transplant community is familiar with the intuition of MELD. The Vice Chair explained that practitioners are largely able to estimate a transplant candidate's MELD score prior to inputting the data to receive the MELD score. The member of the community responded that OPOM scores have been scaled to a 3 to 40 score range. The member of the community explained that an OPOM score of 40 should look like a MELD score of 40.

The Vice Chair expressed interest in hearing patient's perspective of MELD compared to OPOM. A member noted that they may be more inclined to trust a physician compared to computer software. The Chair noted that explaining MELD to candidates is complicated.

Another member asked how many transplant candidates does OPOM account for. The member of the community stated that non-HCC exceptions are not included in OPOM. The Chair of the OPTN Pediatric Transplantation Committee noted that ten percent of the waitlist are pediatric candidates, which are not included in OPOM. The Chair of the OPTN Pediatric Transplantation Committee emphasized the importance of considering how to incorporate the pediatric population in OPOM.

A member noted concern for populations who have historically experienced disenfranchisement and mistrust the medical system. The member stated that social determinants of health are very important, but will be much harder to enact in a system like this.

Next steps:

The Committee will continue to discuss OPOM as a potential attribute in the continuous distribution of livers and intestines.

5. Continuous Distribution Attribute: Supply/Demand

The Committee discussed supply/demand as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

Research and input compiled from Committee members prior to this meeting included:

- Current problem
    - Acuity circles (AC) represents a "one size fits all" construct for organ allocation (hard boundary)
    - Organ supply and demand differs geographically
    - AC works well in densely populated areas, less well in regions with big geography
    - Continuous distribution should ensure adequate supply for estimated demand
    - Continuous distribution should provide proximity points to encourage local use of organs
- 50 percent of the United States population lives within 500 miles of Columbus, Ohio
- Considerations on how to estimate organ supply and demand:
    - Vary AC circle sizes based on geography
        - Would not align with the concept of continuous distribution
    - Prevalence of end-stage liver disease
        - Important issue, but not an allocation issue
    - MELD score differences around the country
        - Would mean more travel
    - Regional differences in liver disease mortality
        - Would mean more travel
    - Number of waitlist candidates
        - Could be manipulated
    - Organ supply/demand ratio in a given area
        - Supply could be defined as number of organs procured by an OPO, and demand could be defined as the number of transplant performed by transplant programs in the OPO's area
    - Continuous population density circles around OPO
- There is variability in liver disease across United States' counties
    - Liver disease appears to be more prevalent in the south-east, south-west, and west coast
- Data analyzing eligible deceased donors per 100 eligible deaths show that most deceased donors are in the center of the United States
- Based on previous observations, it is hard to adjust supply/demand without huge logistical effort (flying)
- Other options
    - Adjust circle size per unit population (simple)
        - Give proximity points to edge of circle then decrease per additional population
    - Adjust circle size based on supply/demand ratio around OPO (complex)
        - Supply defined as OPO organs procured
        - Demand defined as transplant performed within an OPO
        - Multiple by a factor (e.g. four times or six times OPO organs) to account for OPO performance, sharing, while providing adequate supply to local transplant programs

        - Supply/demand ratio idea is interesting but anticipate concerns about OPO performance and potential negative impact of aggressive transplant program behavior (reduce supply/demand ratio)
- A model on supply/demand ratio based on OPO organs procured vs transplant performed between 2018-2021. Circle size based on county data to achieve desired number of events.
- Problem with supply/demand concept
    - Complex construct
    - Can be affected by OPO performance
    - Can be affected by transplant program performance
    - Can be affected by personnel (surgeon) changes
    - Multiple factors may need to be adjusted frequently
- Using population density to adjust circle size around OPO
    - Assumes donation rates relatively equal across country
    - Can be calibrated to overcome regional differences
    - More fair than AC
    - No boundaries; can still go beyond circle edge (continuous)
- Conclusions
    - Various options were considered to calibrate supply and demand issues as well as proximity issues (avoid excess flying)
    - All have merit and disadvantages
    - Population density circles were favored since they are easy to understand, calibrate organ supply and demand equitably and can be easily adjusted over time
    - Exact size and weight yet to be determined
    - The Committee may consider incorporating population density circles into continuous distribution

A member of the community suggested using a denominator of potential deceased donors. The member of the community stated this concept would remove OPO performance as a factor. The member of the community stated that demand should be defined as those on the waitlist, not transplants performed.

The Vice Chair asked how Hawaii, Puerto Rico, and Alaska would be addressed in this potential attribute. The Chair responded that the circles would need to expand to account for enough population in order to access enough deceased donors. A member of the community suggested that those states could be centered around the closest, largest city in the contiguous U.S.

Another member of the community noted there may be game-ability depending on how demand is defined. A member stated that pure population is a definition that could not be gamed.

Another member noted that about a third of the population in the south are not eligible for transplant because of lack of insurance coverage. The member stated this must be factored in when considering the population that is eligible for transplant. The Chair stated this concept as an attribute is to address proximity.

Next steps:

The Committee will continue to discuss supply/demand as a potential attribute in the continuous distribution of livers and intestines.

6. Continuous Distribution Attribute: Donor Factors

The Committee discussed donor factors as a potential attribute to incorporate into continuous distribution of livers and intestines.

Summary of discussion:

Research and input compiled from Committee members prior to this meeting included:

- Currently, liver allocation policy utilizes donation after circulatory death (DCD) donors and age less than 70[4]
- Donor factors as a potential attribute in continuous distribution may impact the goals of patient access and placement efficiency
- Proof of concept: A study placed deceased donors and waitlist candidates into five groups of increasing risk for graft and used a mixed integer programming optimization model to generate allocation rules which maximized graft survival at five and eight years.[5]
- Other existing scores
    - Donor risk index (DRI)[6]
    - D-MELD[7]
    - Pediatric survival outcomes following liver transplant (P-SOFT) score[8]
    - Balance of risk (BAR) score[9]
    - United Kingdom-donation after circulatory death (UK-DCD) score[10]
- Published models for consideration
    - DRI
        - Variables not clinically relevant or impractical: Includes donor race, share type, cold ischemic time, Older Data, hepatits C virus (HCV)-era
        - Performance in current era may be suboptimal
    - Current SRTR risk adjustment model for organ yield
        - Multiple factors and performance not necessarily better
        - Has components such as donor race, employment
        - Donor drug use and diuretic use may be incompletely recorded
        - Certain factors (e.g., candidate education and employment status) do not relate to a donor specific model
        - Includes variables with missing data
    - ID^{2}EAL score[11]
        - Assessment of donor quality and risk of graft failure after liver transplantation
        - Examined donor factors in current era; Based on data between 2013 – 2019
        - Primary outcomes: graft failure within one year after liver transplant
        - Exclude: living liver donation transplant, HCV

[4] OPTN Policy 9.8: Liver Allocation, Classifications, and Rankings as of November 2022.
[5] Kling, C., Perkins, J., Biggins S., et al. Building a Utility-based Liver Allocation Model in Preparation for Continuous Distribution. Transplant Direct. 2022 Jan 13;8(2):e1282. doi: 10.1097/TXD.0000000000001282.
[6] Feng, S., Goodrich, N., Bragg-Gresham, J., et al. Characteristics associated with liver graft failure: the concept of a donor risk index. Am J Transplant. 2006 Apr;6(4):783-90. doi: 10.1111/j.1600-6143.2006.01242.x.
[7] Halldorson, J., Bakthavatsalam, R., Fix, O., et al. D-MELD, a simple predictor of post liver transplant mortality for optimization of donor/recipient matching. Am J Transplant. 2009 Feb;9(2):318-26. doi: 10.1111/j.1600-6143.2008.02491.x.
[8] Rana, A., Pallister, Z., Guiteau, J., et al. Survival Outcomes Following Pediatric Liver Transplantation (Pedi-SOFT) Score: A Novel Predictive Index. Am J Transplant. 2015 Jul;15(7):1855-63. doi: 10.1111/ajt.13190.
[9] Dutkowski, P., Oberkofler, C., Slankamenac, K., et al. Are there better guidelines for allocation in liver transplantation? A novel score targeting justice and utility in the model for end-stage liver disease era. Ann Surg. 2011 Nov;254(5):745-53; discussion 753. doi: 10.1097/SLA.0b013e3182365081.
[10] Schlegel, A., Kalisvaart, M., Scalera, I., et al. The UK DCD Risk Score: A new proposal to define futility in donation-after-circulatory-death liver transplantation. J Hepatol. 2018 Mar;68(3):456-464. doi: 10.1016/j.jhep.2017.10.034.
[11] Asrani, S., Saracino, G., Wall, A., et al. Assessment of donor quality and risk of graft failure after liver transplantation: The ID^2 EAL score. Am J Transplant. 2022 Sep 2. doi: 10.1111/ajt.17191.

        - Identified factors that matter: cause of death CVA, DCD, Insulin dependent diabetes
        - Identified that deceased donor age does not matter as much as it did previously; However, deceased donor age matters more for DCD donors compared to DBD donors
        - Observed that as the height of the deceased donor decreases, the risk associated with it increases; This also matters more for DCD donors
- Suggested ways to incorporate into continuous distribution
    - High score donor goes to closer candidates to mitigate cold ischemia time
    - Candidates opt in for a specified score, sign a consent, and appear on match runs for those donors
    - Need to consider whether distance, time, or predicted cold ischemia times are used as proximity
    - Need to consider whether to incorporate on a scale zero to one hundred versus categories of donor risk
    - Need to consider donor factors only versus donor-recipient matching
- Benefits of incorporating donor factors into continuous distribution
    - Access to transplant: Provide opportunity for candidates with lower MELD scores to have the option for receiving a "high risk donor"
        - Candidates that are sicker than true MELD score
        - Additional points for candidates willing to take a high risk donor (i.e. DCD)
        - Similar to flagging candidates on the waitlist for expedited offers
    - Improve placement efficiency
        - Allocating organs not commonly accepted for higher MELD candidates
    - Maximize organ utility or longevity
        - Direct organs to candidates who are likely to benefit most (e.g. life-years gained)
- Disadvantages of incorporating donor factors into continuous distribution
    - Need data to determine whether incorporating donor factors would disadvantage higher MELD candidates
        - Sicker than MELD have higher waitlist mortality
        - Need data to determine whether higher MELD candidates would get other offers since they may not accept these offers
        - Turn down for these kinds of organs for candidates with MELD 35+ may already be happening
    - Program outcomes
        - Weighting analysis may help adjust
        - E.g. Allowing suboptimal/DCD organ to stay close to donor hospital/low MELD candidate provides an acceptable risk of graft failure as compared to same organ in high MELD candidate or traveling further, etc.

The Vice Chair stated that the current donor factors that are utilized for liver allocation (DCD and age over 70) have been valuable for access and improved efficiency. The Vice Chair stated that similar advantages may appear if candidates are offered the opportunity to sign up for higher risk deceased donor livers. The Vice Chair stated concern on trying to incorporate recipient characteristics at the same time. The Vice Chair stated that they view incorporating donor factors into a points-based allocation system as candidates deciding what score for a high risk donor they are willing to accept. A member stated that ID^{2}EAL was designed to be a donor factor model.

The Chair asked whether there is data to compare risk of ID^{2}EAL score versus risk of being on the waitlist. A member agreed that data is needed, and added that comparing ID^{2}EAL score of a deceased donor liver to a living donor liver is another next step.

An SRTR representative asked why the ID^{2}EAL score did not include percent of macro fat or donor international normalized ratio (INR). A member responded that the performance of the model did not change with the incorporation of macro fat. The member responded that INR was not reviewed. The SRTR representative responded that INR creates a decent hazard ratio for graft failure. The SRTR representative stated this could work similar to the concept of mandatory offer filters in which transplant programs in the local area could be offered any liver with any ID^{2}EAL score, but outside of a certain range transplant programs would not be offered specific ID^{2}EAL score livers based on past acceptance behavior.

Another member stated they envision utilizing ID^{2}EAL score for the candidates who would really benefit from accepting a high risk deceased donor liver, not for all candidates.

A member stated that the field of DCD transplant is rapidly changing due to normothermic regional perfusion (NRP) and ex vivo utilization. Another member responded that the reference deceased donor may change each year, therefore the risk may change as well.

Next steps:

The Committee will continue to discuss donor factors as a potential attribute in the continuous distribution of livers and intestines.

7. Continuous Distribution Attribute Re-cap Presentations

The Committee reviewed their discussions from previous attribute presentations. The Committee reviewed public comment feedback from the *Continuous Distribution of Livers and Intestines Concept Paper* for each attribute.[12]

Summary of discussion:

A member asked what the goal of continuous distribution is. The Chair stated that there may not be one ultimate goal for converting liver and intestine allocation into a points-based system. The Chair explained that there are many goals that the Committee may determine to focus on. The Chair stated that attributes selected for inclusion into the first version of continuous distribution should have justification for being important to the system and protect special populations. The Chair opined that waitlist mortality and medical urgency may likely have the largest amount of weights in a points-based system. The Chair stated that the Committee will determine this during the phase of the project.

A member stated that a goal of converting to a points-based allocation system may be to ensure the outcomes in the current system are preserved.

Another member asked for more information on how modeling a points-based system will be performed during the project's development. Staff will follow up with more information on future modeling requests and reports.

A member asked if there is an appropriate number of attributes to include in the first version of continuous distribution. Staff responded there is not a pre-determined number of attributes and that the Committee should determine benefit and feasibility of including each attribute in order to make a

12 OPTN Liver & Intestinal Organ Transplantation Committee, *Concept Paper,* Continuous Distribution of Livers and Intestines. Public Comment period August 3, 2022 – September 28, 2022. Available at https://optn.transplant.hrsa.gov/

decision. The Vice Chair noted that each attribute will align with one of the five goals, and some goals will have more attributes than others.

Potential attribute: Social Determinants of Health

Recap of previous discussions[13]:

- The Committee must demonstrate a connection between social determinants of health and medical criteria
- OPTN allocation policy is specific to candidates on the waitlist
- Significant evidence of the association of social determinants of health affect outcomes and access to care in the general population and a myriad of health contexts
- There are numerous existing indices that express risk in communities and are likely a proxy for multiple factors
- Deprivation levels are heterogeneously distributed across the U.S.
- Existing evidence of an association of area-level deprivation and liver transplant recipient outcomes
    - Higher wait list mortality and removal
    - Inferior post-transplant survival
    - Higher underlying liver disease in high deprivation communities
- Efforts to measure risks at the individual level and the strength of area measures may be important to specify candidates that would benefit in allocation
- Recommend OPTN acquire patient-specific data to validate correlation between aggregate measures and specific patients
    - If this can show strong level of correlation, then it is a stronger case to incorporate into allocation
- Recommend SRTR include risk-adjustment in pre/post-transplant outcomes monitoring based on social determinants of health factors
- Analyze data related to the interplay of distance from candidate address to transplant program and estimated candidate deprivation
- Even if the aggregate models used to measure social deprivation (i.e. ADI, SDI, GINI index, etc.) are not ready to be included in allocation, Committee could consider incorporating priority for candidates with estimated low social determinants of health based on an ethical argument

A member of the community suggested the Committee propose for the OPTN to collect the physical address of transplant candidates. Another member of the community agreed. The member of the community noted that there have been recommendations that data at the Census Tract level are sufficient for policy implementation. The member of the community noted that while this recommendation may not be applicable to the transplant population, there is a precedent. The member of the community noted that the proposed data collection would be prospective as retrospective data collection would be difficult.

[13] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* August 19, 2022 & September 9, 2022. Available at https://optn.transplant.hrsa.gov/

An SRTR representative stated that the SRTR utilizes every data point available to risk stratify. A member of the community clarified that the ask of risk adjustment by SRTR is to include deprivation indices derived from zip code level data.

Potential Attribute: Post-Transplant Survival/Futility

Recap of previous discussions[14]:

- The Committee will need to define post-transplant survival (e.g. 3, 5, or 10 years?) noting that longer time horizons are more difficult to predict accurately
- The Committee will need to consider whether post-transplant survival should be incorporated on a continuous scale, categorical basis, or as a futility threshold
- Futility: If included, need to define possible threshold. Historically, a concept of 50 percent survival at five years was proposed, and there is empirical evidence that this threshold appropriately balances harm to the waiting list
- Given the organ shortage, if futile transplant can be avoided, this may help other candidates receive a transplant who may derive a larger transplant benefit
- Potential scores
    - Existing risk stratification is suboptimal
    - Candidates score for futility
        - LiTES Score[15]
        - Baylor Model[16]
        - SRTR Model[17]
- Would a "futile" transplant at one transplant program be similarly "futile" at another?
- Would a futility threshold (e.g. 50 percent at five year) reduce or eliminate access to liver transplant for candidates who actually do derive benefit from transplant?
- What are the intended and unintended consequences of deprioritizing candidates re-listed for liver transplant, older age candidates, and candidates with nonalcoholic steatohepatitis (NASH)?
- There has been mixed opinions on incorporating. More support for identifying the futile transplant. If incorporated, recommend low weight given predictive performance (discrimination) of current models.
- Additional analysis and simulation may be needed.
- Can a model be refined or customized so it is more appropriate for allocation in a continuous system than existing models?

The Chair stated that there may be literature under review that developed an estimated post-transplant survival (EPST) score for liver candidates. The Chair suggested keeping post-transplant survival as a potential attribute until future literature could be reviewed.

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[14] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* June 24, 2022 & July 8, 2022. Available at https://optn.transplant.hrsa.gov/

[15] Goldberg, D., Mantero, A., Newcomb, C., et al. Predicting survival after liver transplantation in patients with hepatocellular carcinoma using the LiTES-HCC score. J Hepatol. 2021 Jun;74(6):1398-1406. doi: 10.1016/j.jhep.2020.12.021.

[16] Asrani SK, Saracino G, O'Leary JG, Gonzalez S, Kim PT, McKenna GJ, Klintmalm G, Trotter J. Recipient characteristics and morbidity and mortality after liver transplantation. J Hepatol. 2018 Jul;69(1):43-50. doi: 10.1016/j.jhep.2018.02.004.

[17] Scientific Registry of Transplant Recipients, SRTR Risk Adjustment Model Documentation: Posttransplant Outcomes. Available at https://www.srtr.org/tools/posttransplant-outcomes/.

A member noted that liver allocation currently does not include post-transplant survival, and other organ-specific allocation systems do incorporate post-transplant survival. The member stated this will be an important decision.

This Vice Chair suggested that post-transplant survival could be addressed in two separate attributes, futility and utility. The Vice Chair explained that points could be given to candidates whose transplant would be considered not futile, and points given on a more continuous basis for candidates who have a longer predicted longevity of graft function. The Vice Chair noted that patient feedback has supported the inclusion of post-transplant survival. The Vice Chair suggested the Committee may consider focusing on determining whether futility may be incorporated as an attribute.

Another member suggested narrowing the scope to address the most futile transplants. The member stated that a five-year post-transplant survival should not be considered futile. The member stated that trying to determine five-year post-transplant survival is very difficult due to many variables, such as cancer, and may not be ready to be addressed in time for the first version of continuous distribution of livers and intestines. The member suggested the Committee should discuss how pre-transplant illness may predict early post-transplant outcomes.

A member stated that more data needs to be reviewed to aid the Committee in determining whether short-term futility is meaningful.

Another member stated there is not currently a great model to predict futile transplants.

A member questioned whether it is the role of an allocation system to dictate what is deemed as a futile transplant, rather than allowing medical professionals to use their expertise and judgement on case-by-case bases.

The Chair stated that futility may not be impactful due to the probable weight of medical urgency in a composite allocation score.

Potential Attribute: Prior Living Donor Priority

Recap of previous discussions[18]:

- The Living Donor Committee offered four global recommendations regarding prior living donor priority:
    - Prior living donors should receive priority if they are listed for transplant
    - All prior living donors should receive priority for any organ needed
    - Prior living donor priority should not have a time restriction
    - Prior living donors should not be valued differently based on organ donated
- Supportive of including some form of prior living donor priority
- Some questions about live vascularized composite allograft (VCA) donation and potential for candidates donating a VCA to get future priority
- Some questions about providing priority regardless of original organ donated

A member stated the Committee may consider giving priority to individuals who are powers of attorney who have permitted their loved ones to donate. The member noted that some international transplant systems incorporate priority such as this. The Vice Chair responded that monitoring would be difficult.

The Chair stated the Committee may consider developing tiers for various prior living donor priority. The Vice Chair stated that creating tiers would become a values-based judgement. The Vice Chair stated that

[18] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* July 8, 2022 & July 22, 2022. Available at https://optn.transplant.hrsa.gov/

additional priority for prior living donors may be accounted for within the context of medical urgency. The Vice Chair stated that a simple way to operationalize this potential attribute may be to have flat rate of priority for any living donor, at any time.

The Chair asked for information on how prior living donor priority is currently incorporated in to kidney allocation. A member of the community responded *that Policy 8.5: Kidney Allocation Classifications and Rankings* outlines the allocation sequences for prior living donors.

Potential Attribute: Surgical Complexity and Re-transplant

Recap of previous discussions[19]:

- Surgical complexity:
    - May portend worse outcomes
    - Data is sparse
    - Should not be considered as a potential attribute
- Re-transplant:
    - Expedited access in current policy (Policy 9.1: Status and Score Assignments & 9.5: Specific Standardized MELD or PELD Score Exceptions)
        - These candidates should continue to receive additional priority
        - Consider extending MELD 40 priority from 15-30 days post-transplant for those recipients with Hepatic Artery Thrombosis (HAT) detected beyond 14 days
        - Provide recourse for those recipients who might be denied an exception appeal
    - Non-expedited access
        - In general, additional priority should not be given to recipients who had a prior period of successful graft function
        - But maybe different for pediatric populations?
    - Portal vein thrombosis (PVT)
        - Patients with complex PVT do not require prioritization

A member asked if incorporating surgical complexity would include situations where a hepatecomy was performed due to other reasons besides transplant, such as cancer. Another member responded that it could be considered but data to determine appropriate prioritization may be limited.

The Chair stated that current liver allocation policy seems to provide sufficient guardrails needed for those candidates in need of re-transplant. The Chair stated that surgical complexity can be subjective so determining additional priority may be difficult. Another member agreed that a surgically complex case may require more time for technical scenarios rather than additional priority in the context of allocation.

Potential Attribute: Frailty

Recap of previous discussions[20]:

- Frailty is just one metric of physical fitness
- Increased mortality in waitlisted candidates with poor physical fitness
- Post-transplant mortality may be acceptable among frail & sarcopenic recipients
    - But increases the cost of care after transplant

[19] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* July 22, 2022 & August 5, 2022. Available at https://optn.transplant.hrsa.gov/

[20] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* August 5, 2022 & August 19, 2022. Available at https://optn.transplant.hrsa.gov/

- Available metrics for physical fitness and implementation challenges
    - Objective vs. subjective metrics
    - Fitness can improve with physical training (can be manipulated?)
- Differences between sexes
    - Frailty more in females; sarcopenia more in males
    - Ethnicity less studied
- Do not support including this attribute in the first iteration of continuous distribution for some of the following reasons:
    - Unclear if should be factor into waitlist mortality, post-transplant outcomes, or both
    - Subjective measurement techniques, potentially manipulated
    - Data not currently collected by OPTN
- Recommend collecting data on the six minute walk

A member stated that the six-minute walk may be the most practical measure. The member noted that it is currently collected for lung candidates and is well validated. The member expressed concern regarding not utilizing liver frailty index (LFI). The member stated a lot of work has been done for LFI and it is well validated. The member noted LFI may have game-ability concerns as well as additional data collection would be needed. Another member stated that LFI does not need to be disregarded; however, this discussion is to focus on whether it is currently feasible to incorporate into continuous distribution at this point in time.

Staff noted that the OPTN Lung Transplantation Committee is developing guidance on standardizing the six-minute walk.

The Vice Chair asked whether collecting data on the six minute walk test for liver candidates would be required or optional. A member stated that if the six minute walk data is optional then the results may be skewed due to only data entry for those candidates who are frail.

Another member asked when the six minute walk data should be collected. A member suggested that the six minute walk data should be collected at time of listing and at the six month mark to understand a trajectory. The member noted that candidates may be undergoing pre-habilitation, so it would be important for the Committee to consider how to ensure candidates are not being penalized for health improvement.

Another member asked how the six minute walk test would apply to individuals with mobility issues. A member agreed that is an outstanding issue, and one of the reasons this attribute may not be ready to incorporate in the first version of continuous distribution.

Potential Attribute: Donor-Recipient Size Matching

Recap of previous discussions[21]:

- This is a problem of access to appropriate-sized grafts. If two recipients have the same MELD, the smaller will have a more difficult time finding a liver.
- This is not a problem of priority (i.e. who is at the top of the list)
- Short stature candidates have lower transplant rates, longer wait times, and higher mortality on the waitlist

[21] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summary,* September 30, 2022. Available at https://optn.transplant.hrsa.gov/

- The NASEM Report recommended to "modify the MELD scoring system for liver allocation and prioritization or establish an alternative overall prioritization scheme to include a modifier based on body size or muscle mass to overcome the demonstrated disparities observed for candidates of smaller size"
- Sex and height are collinear; impact of sex on creatinine was greater than impact of height, so sex was included in MELD 3.0
- MELD predicts death on the waitlist; size is about access to donors
- OPTN Lung Transplantation Committee used *Recipient Height minus Donor Height* to find the proportion of height incompatible donors. No adjustment for ABO, geography, etc.
- Liver: body surface area (BSA) Ratio (*Donor BSA divided by Recipient BSA*), range: 0.68-1.25
- Calculated proportion of BSA compatible and then in-compatible donors

The Chair stated that split livers and donor-recipient size matching are related attributes. A member of the community stated that split livers can be part of the solution. The member of the community explained that split liver transplants are not accessible to every transplant candidate.

A member asked whether OPOM addresses donor-recipient size matching. Another member of the community stated that height, weight, and BSA can be added to OPOM to analyze whether there is an impact. The Vice Chair stated that this is an access problem, not a priority problem so incorporating it into OPOM may cause inefficiencies. The member of the community responded that OPOM would only address this problem if it found that smaller candidates have a higher waitlist mortality rate. Another member responded that donor-recipient size matching would help address some inefficiencies, rather than prioritizing candidates based on size.

Potential Attribute: Willingness to accept split liver transplantation

Recap of previous discussions[22]:

- Split liver transplantation is a critical means of access for transplant for small children
    - Split liver transplantation survival equivalent to living liver donation transplant
    - Split liver transplantation confers survival advantage for children less than seven kilograms
- Split liver transplantation is underutilized relative to its potential impact on children and adults
    - Historically ~3 percent of transplants, declined to ~2 percent in AC implementation; Split liver transplantation performed at ~20 transplant programs
- Policy initiatives/variances have not increased split liver transplant utilization
    - Current allocation policy complicates split liver transplant utilization, especially related to placement of second segment
- Significant transplant program concerns remain regarding split liver transplantation complexity/risk
    - Split liver transplantation for adults restricted in practice to lower MELD candidates; adult candidates rarely initiate split liver transplantation
- Deceased donors that meet "splittable" criteria should trigger a primary match run with allocation points given to pediatric and small adult candidates who will accept a split liver transplantation.

[22] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* September 9, 2022 & September 30, 2022. Available at https://optn.transplant.hrsa.gov/

    - Current “splittable” criteria: less than 40 years of age, single vasopressor or less, transaminases less than or equal to 3 times normal, body mass index (BMI) less than or equal to 28
- Majority of split liver donors are age less than 30, BMI less than or equal to 25[23]
- Allocation points provided to pediatric and small adult candidates should be stratified with greatest number of points given to pediatric candidates less than 7 kilograms (or perhaps less than 2 years of age).
- Allow expedited placement of second segment on a separate match run, to transplant programs and candidates who will accept split.
- Give “proximity” points to the primary transplant program (or associated adult transplant program of a pediatric transplant program) in the match run for the second segment.
- Consider additional points for candidates at a transplant program with history of split liver transplantation utilization.
- Recommended best model for how to incorporate split livers:
    - Provide stratified allocation points to children and small adults on match run for deceased donors meeting “splittable” criteria; allocate second segment on separate match run; provide ”proximity points” to primary transplant program for second segment; consider additional points for candidates at transplant programs with history of split liver transplantation

The Vice Chair suggested the Committee should consider how to ensure a candidate is prioritized enough to receive a split liver. The Vice Chair explained that a candidate may be willing to accept a split liver, but priority is still needed to have access to a split liver offer. A member responded that ways to prioritize the primary transplant program or ways to restrict offers to transplant programs with histories of accepting split livers may be an option.

A member stated that if split liver transplantation is a valuable resource to the transplant community, then the Committee should develop a solution to prioritize split liver usage.

Another member stated there is data to show that transplant programs that do not perform split liver transplantation have been observed to have higher pediatric waitlist mortality rates. The member also noted that there is a fundamental structural problem that needs to change with the match run in order to make split liver allocation more expedient.

A member asked if livers could be allocated to pediatric candidates, split, and then allocate the remaining segment to an adult rather than giving the adult the option to split the liver. Another member responded that data shows there are about one hundred right liver segments a year that are discarded due to the current allocation requirements.

A member suggested the idea of liver candidates partnering up and combining MELD scores in order to receive priority. The member gave an example of two small statured candidates with MELD scores of 15 could be partnered to have a combined MELD score of 30 in order to gain priority and access. The member noted this may be difficult to operationalize.

A member of the OPTN Pediatric Transplantation Committee noted that there are anywhere between 100 and 300 pediatric liver candidates under seven kilograms. The member of the OPTN Pediatric Transplantation Committee stated that their mortality is closer to fourteen to fifteen percent. The

[23] Perito, E., Roll, G., Dodge, J., et al. (2019). Split Liver Transplantation and Pediatric Waitlist Mortality in the United States: Potential for Improvement. *Transplantation*, *103*(3), 552–557. doi: 10.1097/TP.0000000000002249

member of the OPTN Pediatric Transplantation Committee stated that the majority of these small pediatric candidates are ideal for split liver transplant, so adequately prioritizing and mandating split livers would help address waitlist mortality in that population. A member stated that the waitlist mortality may be occurring at transplant programs that do not perform split liver transplantation. A member of the community added that pediatric transplant programs should be held accountable to perform split liver transplantation.

Potential Attribute: HCC Stratification

Recap of previous discussions[24]:

- Currently, all candidates qualifying for standardized HCC exception receive MTS -3
- Currently 13-20 percent of the liver waitlist & transplants
- There are low risk and high risk HCC candidates
- Waitlist dropout risk can be stratified
- Prioritizes HCC candidates based on urgency/benefit rather than one common score
    - Addresses Final Rule: prioritizes candidates by urgency, optimizes utility of transplant, preserves access for candidates with HCC
- Increasing waitlist dropout risk = urgency
    - At a certain threshold, higher waitlist risk associated with increased post-transplant mortality & HCC recurrence
    - May need to consider post-transplant outcome (utility) and overall transplant benefit
        - Current system sets this ceiling at AFP >1000, outside Milan, extrahepatic disease
- Matching HCC waitlist dropout risk to non-HCC
    - Tempting but may decrease access to transplant further for HCC candidates
        - HCC waitlist dropout risk matched to MELD is generally low (most MELD-HCC is less than 20)
    - HCC not just about waitlist dropout but also access/window for transplant
- Model should include:
    - MELD
    - Tumor size/burden
    - AFP
    - Time served
        - If not, then may disincentivize locoregional treatment to control tumor
- Simple stratification may be preferable to more complex algorithms
    - Added complexity not necessary to appropriately risk stratify
    - Categories versus continuous scoring
    - Adding in dynamic variables (tumor growth) may disincentivize treatment

A member stated that the Committee should consider keeping HCC candidates separate and stratify against themselves, rather than interdigitating among non-HCC candidates. The member explained the different stratifications of HCC candidates would receive different levels of priority. The member stated that models that interdigitate HCC candidates with non-HCC candidates, HCC candidates tend to receive a MELD Score equivalent to 15 or 20. The member stated that waitlist mortality and waitlist dropout is not fully representative of the HCC candidate's need for transplant or actual dropout risk.

[24] OPTN Liver & Intestinal Organ Transplantation Committee, *Meeting Summaries,* September 16, 2022 & September 30, 2022. Available at https://optn.transplant.hrsa.gov/

Another member asked if there is data to understand why HCC candidates drop off the waitlist. The member explained understanding waitlist dropout reasons may be beneficial to figuring out priority. A member responded that HCC candidates dropout because they are out of HCC criteria.

Another member stated that the simplest solution would be to create three stratifications among HCC candidates. A member noted that the waitlist dropout score for HCC model[25] may be the simplest solution to incorporate. The member noted that this model is continuous, but it was stratified into quartiles.

The Vice Chair asked whether OPOM could be utilized for just HCC candidates. A member of the community stated that OPOM could be utilized for only lab candidates.

Next steps:

The Committee will continue to discuss which attributes should be included in the development of continuous distribution of livers and intestines.

8. Attribute Benefit versus Feasibility

In small groups, the Committee reviewed and discussed all identified potential attributes. The Committee opined on the benefit and feasibility of incorporating each potential attribute into continuous distribution. The results of these discussions lend to the conversations detailed below.

Summary of discussion:

Surgical Complexity and Re-transplant

The Chair noted that when their group was discussing the benefit and feasibility of surgical complexity and re-transplant, they favored re-transplant as an attribute rather than surgical complexity.

The Vice Chair stated that priority for re-transplant is addressed in current allocation policy.

The Committee agreed that the current policies regarding urgent re-transplants should be addressed, and possibly modified, with continuous distribution. The Committee agreed that re-transplant and surgical complexities are not needed as attributes in the continuous distribution of livers and intestines.

Social Determinants of Health

Group discussions indicated that while this attribute may be beneficial, the feasibility of incorporating into continuous distribution was low.

The Chair stated that there seems to be consensus that social determinants of health is not ready to be incorporated as an attribute in the first version of continuous distribution. An SRTR representative urged the Committee to consider what data should be collected to ensure social determinants of health could be incorporated into allocation systems in the future.

The Chair noted the Committee will continue to discuss what data collection is necessary and have further conversations with the OPTN Data Advisory & Policy Oversight Committees.

Frailty

Group discussions indicated that while this attribute may be beneficial, the feasibility of incorporating into continuous distribution was low.

[25] Mehta, N., Dodge, J. L., Roberts, J. P., & Yao, F. Y. (2021). A novel waitlist dropout score for hepatocellular carcinoma - identifying a threshold that predicts worse post-transplant survival. Journal of hepatology, 74(4), 829– 837. https://doi.org/10.1016/j.jhep.2020.10.033

A member stated that frailty is not ready to be incorporated into the first version of continuous distribution of livers and intestines.

The Committee agreed that frailty can be removed from the list of potential attributes.

An SRTR representative suggested the Committee consider determining best practices on how to consistently assess frailty across transplant programs. A member agreed and noted the Committee may need to consider data collection.

Post-transplant Survival

A member suggested the Committee consider splitting this attribute into addressing futility in the short-term and utility in the long-term. The member stated that futility in the short-term may be a first step.

Another member stated that incorporating post-transplant survival may improve utility outcomes.

The Chair stated that this attribute may need a placeholder until forthcoming data is released.

A member asked if LSAM is able to model post-transplant survival. An SRTR representative responded that LSAM can model post-transplant outcomes.

Another member stated that one-year post-transplant survival may be the easiest to estimate, but the least helpful. The member explained that for DCD transplant, three-year outcomes are more important than one-year.

A member asked how would to differentiate between a 92 percent post-transplant survival and an 88 percent post-transplant survival. Another member suggested age could be used, but noted that the Committee has previously not utilized candidate age in allocation.

The Vice Chair suggested the Committee could consider focusing on futility, such as 50 percent survival at 90 days, rather than utility. The Vice Chair stated that the liver transplant community appears to be able to predict futility at bedside. The Vice Chair stated that perhaps liver allocation does not need post-transplant survival as an attribute. Another member agreed and added that lung utilized post-transplant survival in allocation in order to address a post-transplant survival deficit. The member noted that the post-transplant outcomes in lung were not as good as post-transplant outcomes in liver transplantation, which may have necessitated the need for including into lung allocation. A member noted that there are guardrails, such as payer reimbursement and program-specific reports (PSRs), that are already in place.

Another member asked whether the community is expecting post-transplant survival to be incorporated into continuous distribution. A member responded that post-transplant survival should be incorporated into continuous distribution because it is needed, beneficial, and feasible, not because of an expectation.

Another member stated that transplant professionals should be able to use their expertise to determine futility, and titrating post-transplant outcomes does not benefit innovation in the field.

The Vice Chair stated that input from the patient perspective is needed. A member stated that as a transplant candidate, the focus was on surviving to the next month in order to receive a transplant, not on long-term survival post-transplant. Another member noted that patients advocate for more transparent information. The member stated that some information may reflect negatively on the quality of the transplant program, but there is additional context needed. The member explained that perhaps a transplant program is utilizing innovative techniques that impact certain metrics.

A member stated that a patient's perspective on post-transplant survival may change based on the situation. Another member noted a research study that analyzed a range of populations in the

transplant community regarding post-transplant survival. The member stated that transplant candidates sought transplantation even if the post-transplant survival was estimated to be low.

A member stated that futility may be more connected with transplanting candidates with alcohol related liver disease who subsequently relapse after transplant. The member stated that it may be difficult to systematically measure futility in an allocation system.

Another member suggested that data should be reviewed on a cohort of transplants that would be considered futile.

Donor Factors

A member stated that the two most important considerations in donor factors are having some type of extra proximity boost for the most marginal organs, and directing the highest quality donor organs to specific populations of need. The Chair agreed. Another member agreed and stated that some donor factors are accounted for in other attributes, such as willingness to split a liver.

Another member suggested the Committee should analyze whether incorporating donor factors into allocation may impact liver discards.

The Chair asked whether donor factors should be a stand-alone attribute, since aspects of it are incorporated into other attributes, such as split liver. A member responded and stated that there are other donor factors that do not overlap with currently identified attributes, such as renal function. Another member responded that donor factors could be implemented by having candidates identify whether they are willing to accept a high risk organ offer. The member noted that the definition 'high risk' may change over time as the community learns more. The member noted that donor factors may be addressed through proximity and access.

An SRTR representative suggested the Committee could consider identifying marginal livers, then identify candidates who should receive priority for those livers. The Chair agreed. The Chair added concern that placing numbers on livers may result in unnecessary discards.

A member stated that the DCD field is evolving, so creating a continuous model may be time-consuming to create and inevitably will need to be reworked in the short term due to new research and knowledge.

The Committee agreed to remove donor factors as a potential attribute, and focus on addressing donor factors in other related attributes.

Prior Living Donors

The Committee agreed to include prior living donors as an attribute in continuous distribution of livers and intestines.

OPOM

The Chair noted support for OPOM. The Chair stated that OPOM has matured since the first presentation received, and noted opportunity to continue to improve it. The Chair noted that when MELD was first introduced to the community, it appeared to be revolutionary but now it is standard practice.

A member stated that machine learning techniques have improved over the last five to ten years. The member stated that machine learning may also help the community develop better models.

The Chair noted support for how OPOM interdigitates HCC with non-HCC candidates.

A member of the community stated they will follow-up with the Committee's request on modifying OPOM, such as removing age and adding in height/weight.

Another member asked if post-transplant survival is incorporated in OPOM. The member of the community stated that OPOM predicts waitlist mortality, so post-transplant survival is not included.

The Chair stated the Committee could consider a placeholder for OPOM to allow for more time to understand the system and see how it adapts.

The Vice Chair suggested the Committee should decide whether they want to utilize OPOM as a way to address several components of continuous distribution, or address these components individually in order to have the ability to modify certain levers in the future. The Vice Chair added this may depend on OPOM's functionality.

A member asked for more information on the type of events OPOM is good at predicting and those that it is not as good at predicting. The member of the community stated that a low frequency event that OPOM is not good at predicting is pediatric waitlist mortality because there is not enough data. The member of the community stated that relatively frequent events, such as adults being removed from the waitlist list, OPOM is good at predicting that.

Another member asked whether changes to OPOM would have to go through the policy development process if it were incorporated into continuous distribution. Staff responded it depends on how the Committee chooses to incorporate OPOM. The member of the community suggested that the Committee develop a flexible policy to allow for OPOM to be refitted on an annual basis. The Chair agreed and added that if OPOM is included in continuous distribution, then the Committee should develop a policy that does not become too restrictive for adapting.

Other members noted caution for incorporating OPOM due to interpretability and the need for understanding the model better. A member stated that more information will be helpful.

The Vice Chair stated reservations that the only metric that identifies risks of candidates with HCC is AFP. The Vice Chair explained that some tumors do not produce AFP, and there are locoregional therapy considerations. The member of the community stated that the computer decides whether or not to include variables based on whether it is influencing the outcome of interest. The member of the community stated that if certain variables are forced then there may be a decrease in the benefit of the model.

Willingness to Accept a Split Liver

The Chair suggested prioritizing small pediatric candidates for the best "splittable" livers, and prioritizing small adult for allocation of the remaining segment. The Chair stated these are not large populations and they should be prioritized. A member agreed and stated that prioritizing the small adult for the remaining segment is to work towards diminishing the discard rate of the remaining liver segments. The member added that transplant programs that split livers should be identified in order for candidates, especially pediatric candidates, to understand their access to transplant.

Another member stated that there should be no pediatric deaths on the waitlist. The member stated that the best livers should be prioritized for pediatric candidates, especially increasing access to split livers. The member stated that there should be incentives to accept a split liver. The member suggested that the adult transplant programs pair up with pediatric transplant programs to ensure the remaining segment can be placed in a small adult.

A member suggested a separate match run for livers that are identified to be "splittable"

The Chair noted that a criticism of the Region 8 variance was that pediatric transplant programs were moving livers to the adult transplant programs. Another member disagreed with this criticism, stating that the intent is to transplant more pediatric candidates.

The Committee agreed that willingness to accept a split liver should be incorporated as an attribute in order to eliminate pediatric waitlist mortality. The Committee agreed that willingness to accept a split liver may also address donor-recipient size matching for smaller adult candidates as well.

A member noted that the Committee will need to determine guidelines on the location of where the splitting of the liver is performed.

Supply/Demand

A member stated that the feasibility of adjusting circles seems difficult. The member added that proximity points may be a better direction.

The Chair stated that number of deaths may be a better way to define supply because donation rates usually follow death rates. The Chair stated that number of candidates on the waitlist with MELDs of 15 or higher may be a way to define demand.

A member stated that supply/demand may help address some of the logistical issues that have appeared after the implementation of AC.

The Committee agreed to keep the concept of supply/demand as an attribute in continuous distribution.

Next steps:

The Committee will continue to finalize a list of attributes to incorporate into the first version of a points-based allocation system for livers and intestines.

Upcoming Meeting

- November 10, 2022 (teleconference)
- November 18, 2022 (teleconference)

Attendance

- **Committee Members**
  - Alan Gunderson
  - Allison Kwong
  - Bailey Heiting
  - Christopher Sonnenday
  - Colleen Reed
  - Diane Alonso
  - Erin Maynard
  - Greg McKenna
  - James Eason
  - James Markmann
  - James Pomposelli
  - James Trotter
  - Joseph DiNorcia
  - Kym Watt
  - Neil Shah
  - Peter Abt
  - Scott Biggins
  - Sophoclis Alexopoulos
  - Vanessa Pucciarelli
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - John Lake
  - Katie Audette
  - Nick Wood
  - Ryo Hirose
  - W Ray Kim
- **UNOS Staff**
  - Betsy Gans
  - Delaney Niles
  - Erin Schnellinger
  - Jennifer Musick
  - Joel Newman
  - Julia Foutz
  - Katrina Gauntt
  - Krissy Laurie
  - Lindsay Larkin
  - Matt Cafarella
  - Meghan McDermott
  - Niyati Upadhyay
  - Sarah Scott
  - Susan Tlusty
- **Other Attendees**
  - Catherine Kling

- Dave Weimer
- Dimitris Bersitmas
- Emily Perito
- Evelyn Hsu
- Jesse Schold
- Pratima Sharma
- S DeLair
- Samantha Taylor
- Stevan Gonzalez