OPTN

Request for Feedback

Update on Continuous Distribution of Livers and Intestines

OPTN Liver and Intestinal Organ Transplantation Committee

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Contents

Update on Continuous Distribution of Livers and Intestines

Sponsoring Committee: *Liver and Intestinal Organ Transplantation*
Public Comment Period: *January 19, 2023 – March 15, 2023*

Executive Summary

In December 2021, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) began their work to convert the current classification-based allocation system for livers and intestines to a point-based framework, otherwise known as continuous distribution. Continuous distribution will replace the current classification-based approach, which draws hard boundaries between types of candidates (for example, blood type compatible vs. identical; inside vs. outside a circle), with a composite score that simultaneously takes into account donor and candidate attributes. This points-based framework will create a more equitable and transparent allocation system.

This request for feedback builds upon the previous concept paper on the continuous distribution of livers and intestines that was released for public comment in August 2022.[1] The purpose of this request for feedback is to supplement the values prioritization exercise that is currently available for members of the transplant community to complete. The values prioritization exercise asks community members to compare the relative importance of the different factors that will be included in the new allocation system. The results of the values prioritization exercise will provide valuable feedback to the Committee on how to weight the different factors in continuous distribution. In addition, this request for feedback provides an update on the progress the Committee has made on the project thus far, solicits feedback from the community on the Committee's work to date, and outlines the anticipated next steps in the development of the continuous distribution of livers and intestines

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[1] OPTN Liver and Intestinal Organ Transplantation Committee, Concept Paper, Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/fzmjii35/continuous-distribution-of-livers-and-intestines-concept-paper_liver_pc-summer-2022.pdf.

Background

In 2018, the OPTN Board of Directors chose to replace the current classification-based allocation system with a points-based continuous distribution framework.[2] Continuous distribution aims to eliminate the hard boundaries between classifications that exist in the current liver and intestine allocation system, ultimately resulting in more equity for candidates on the waitlist and increased transparency in the allocation of livers and intestines. In addition to the benefits of removing hard boundaries between classifications, continuous distribution also has more potential for flexibility, producing efficiencies not only in allocation but also in policy development and implementation.

In December 2021, the Liver and Intestinal Organ Transplantation Committee (the Committee) began developing a framework for the continuous distribution of livers and intestines. Also in December 2021, the OPTN Board of Directors approved a proposal to establish the continuous distribution of lungs.[3] In addition, the OPTN Kidney Transplantation Committee and the OPTN Pancreas Transplantation Committee are collaborating on a project to convert the kidney and pancreas allocation systems to continuous distribution and the OPTN Heart Transplantation Committee has begun their work on the continuous distribution of hearts, as well. The goal is for all organs to eventually transition to a continuous distribution allocation system.

Purpose

This request for feedback provides updated information on the progress the Committee has made on the continuous distribution project and the anticipated next steps in developing a continuous distribution framework for the allocation of livers and intestines.

In addition, the Committee is seeking the community's feedback on the values-based decisions that are required for the development of a points-based allocation system. Additional feedback on the Committee's progress to date, the plan for the project moving forward, and any other relevant aspects of the larger effort to develop continuous distribution is also encouraged. This is not a final policy proposal and the Committee has not confirmed any specific decisions or recommendations. With such a significant change to the allocation system, community input is particularly important and the Committee is eager for feedback from the transplant community at every step of the project.

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[2] OPTN Board of Directors. 2018, December 3-4. Executive Summary. Available at https://optn.transplant.hrsa.gov.
[3] OPTN Lung Transplantation Committee, *Briefing Paper,* Establish Continuous Distribution of Lungs. Public Comment Period August 3, 2021 – September 30, 2021. https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

What is Continuous Distribution? [4]

A continuous distribution system prioritizes candidates based on a combination of points awarded for factors related to medical urgency, expected post-transplant outcomes, candidate biology, patient access, and the efficient management of organ placement. Continuous distribution will eliminate hard boundaries between classifications, which currently preclude a candidate from being prioritized ahead of candidates on the other side of the boundary, despite other factors that could impact each candidate's prioritization for transplant.[5,6] In a points-based system, candidates will be ranked on a match run based on a combination of donor and candidate clinical characteristics, as well as placement efficiency.

While the concept of a points-based system may seem foreign in the context of liver and intestine, it is already used in some areas of allocation. For example, *OPTN Policy 9.7.A Liver Allocation Points* explains how points are used in the current allocation system to sort candidates within Status 1A and Status 1B. Specifically, Status 1B candidates on a match run are sorted using three different types of points – diagnosis points, waiting time points, and blood type compatibility points. On a particular match run, Status 1B candidates are sorted based on the total number of points they receive across these three categories.

> **Classification-based framework**: A classification-based framework places similar candidates into ordered classifications or groupings. Candidates are then sorted within those classifications. This is the framework currently used to allocate livers and intestines.
>
> **Points-based framework**: A points-based framework assigns a composite allocation score (CAS) to each candidate for each match run. Organs are then offered in descending order based upon the candidate's score for that match run. This concept paper describes a points-based framework for organ allocation, otherwise known as continuous distribution.

This existing policy is an example of a points-based allocation framework. Rather than saying, for example, that *all* blood type identical candidates will be sorted ahead of *all* blood type compatible candidates regardless of other factors, the points based system allows for increased flexibility based on specific candidate characteristics.

The goal of continuous distribution is to convert all aspects of liver and intestine allocation that rely on distinct classifications, such as model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score and distance from donor hospital to transplant program, to a more flexible and transparent continuous distribution system.

Composite Allocation Score

The continuous distribution framework will rank candidates using a composite allocation score, or CAS, that aligns with the different requirements found in the NOTA and the OPTN Final Rule.[7,8] **Figure 1** shows the five sub-scores, or goals, that constitute the overall CAS.

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[4] Continuous distribution aims to create a more fair and patient-focused system for organ allocation. For additional information on the continuous distribution framework and the work of the OPTN, visit http://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/.

[5] J. J. Snyder et al., "Organ distribution without geographic boundaries: A possible framework for organ allocation," Am J Transplant 18, no. 11 (Nov 2018), https://doi.org/10.1111/ajt.15115.

[6] Jon Snyder, "Systems without Geographic Boundaries". Presented to the OPTN Ad Hoc Geography Committee meeting, March 26, 2018.

[7] 42 CFR §121.8.

[8] 42 U.S.C. §274

Figure 1: Components of Composite Allocation Score

These five goals form the basis of the continuous distribution framework.[9] Within each goal, the Committee has identified different potential attributes. Candidates will be assigned a certain number of points for each attribute, which will then be combined to create sub-scores that align with the different goals. One can liken CAS to a hierarchy depicted below in **Figure 2.** At the bottom are the different attributes aligned under the five goals. The goals are then combined to form the CAS.

Figure 2: CAS Hierarchy Depiction
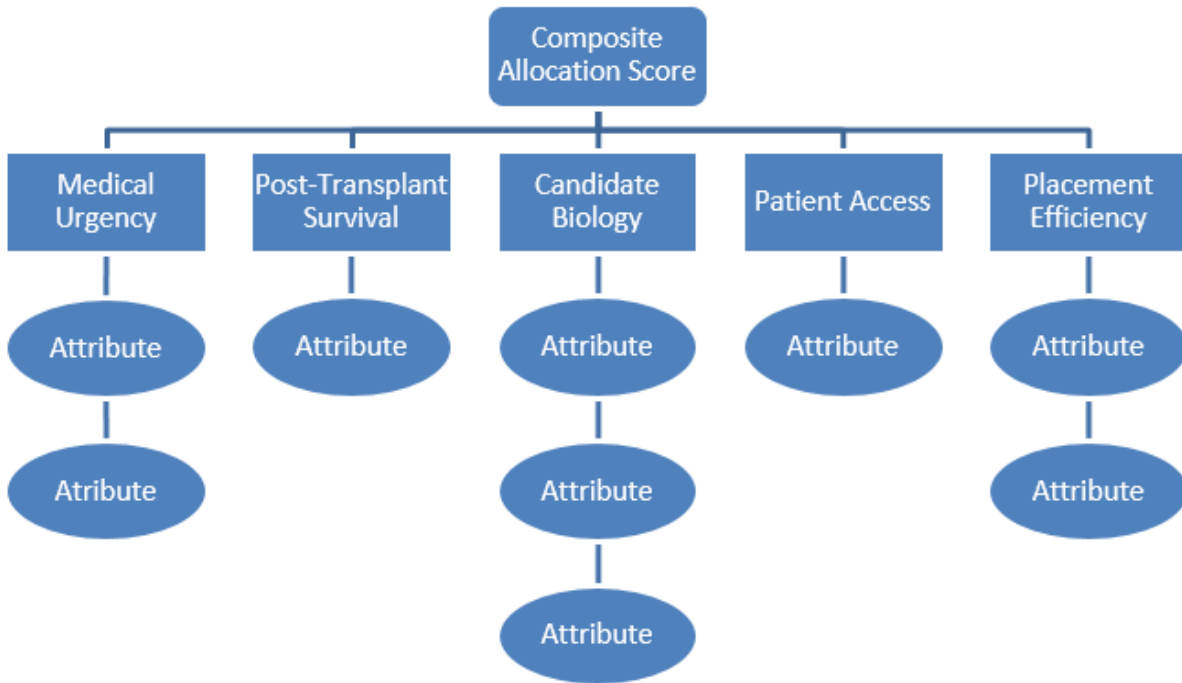
Combining multiple scores allows the OPTN to simultaneously utilize all the factors that must be considered to satisfy the regulatory requirements for organ allocation policies. It will also allow the OPTN to understand the role of each score across organs. For example, some organ systems may place more weight on post-transplant outcomes than other organs. Finally, by constructing the CAS around the performance goals in the OPTN Final Rule, the rationale for compliance will more explicitly align with the requirements in the OPTN Final Rule.[10]

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[9] OPTN Liver and Intestinal Organ Transplantation Committee, Concept Paper, Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/fzmjii35/continuous-distribution-of-livers-and-intestines-concept-paper_liver_pc-summer-2022.pdf

[10] 42 CFR §121.8.

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Figures 3 and 4 show how the current liver allocation system functions and how a potential liver and intestine allocation system utilizing a CAS could work. This is just a rough example, but it depicts how candidates could receive points for different attributes, which are then combined to calculate the overall CAS. The amount of points given to each candidate will depend upon the candidate's specific situation, the rating scale for that attribute, and the amount of weight given to that goal or attribute within the overall CAS.

**Figure 3: Sample Allocation Policy (Current)**

Note that candidates are placed into specific classifications and cannot move between them unless their status changes.

Table 9-11: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates with a MELD or PELD score of at least	And registered at a transplant hospital that is at or within this distance from a donor hospital	Donor blood type	Candidate blood type
1	Status 1A	500NM	Any	Any
2	Status 1B	500NM	Any	Any
3	Status 1A	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
4	Status 1B	2,400NM and candidate is registered in Hawaii or 1,100NM and candidate is registered in Puerto Rico	Any	Any
5	37	150NM	O	O or B
6	37	150NM	Non-O	Any

Figure 4: Example Match Run (Proposed)

Each color represents a different attribute and the length of the bar shows the points credited to that attribute. Note that candidates receive points for multiple considerations and can move up or down depending on each attribute.
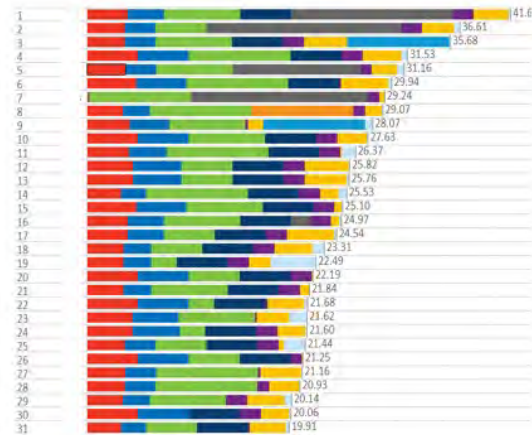
Project Plan

The Committee is tasked with developing a comprehensive proposal for the continuous distribution of livers and intestines, an effort that represents perhaps the most significant change to liver and intestine allocation in recent history. The project will progress through several phases, as seen in **Figure 5**, and detailed in the Summer 2022 concept paper.[11] At this time, the Committee is working to develop rating scales and the relative weights of each attribute or goal in the overall CAS, highlighted in the red box in **Figure 5**.[12]

The previous concept paper focused on identifying the attributes the Committee planned to discuss and asked for community feedback on which attributes should be included in the first iteration of continuous distribution.[13] Since that time, the Committee has narrowed the list of attributes and are moving

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[11] OPTN Liver and Intestinal Organ Transplantation Committee, Concept Paper, Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/fzmjii35/continuous-distribution-of-livers-and-intestines-concept-paper_liver_pc-summer-2022.pdf.

[12] Ibid.

[13] Ibid.

forward with building rating scales and developing relative weights for those attributes they are continuing to consider for inclusion in the first iteration of continuous distribution.
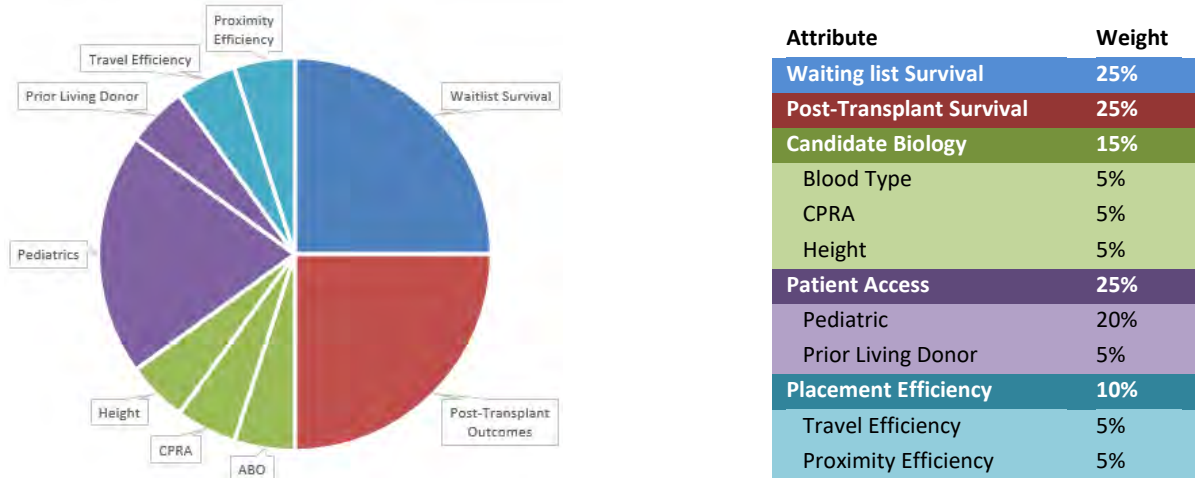
Figure 5: Project Overview
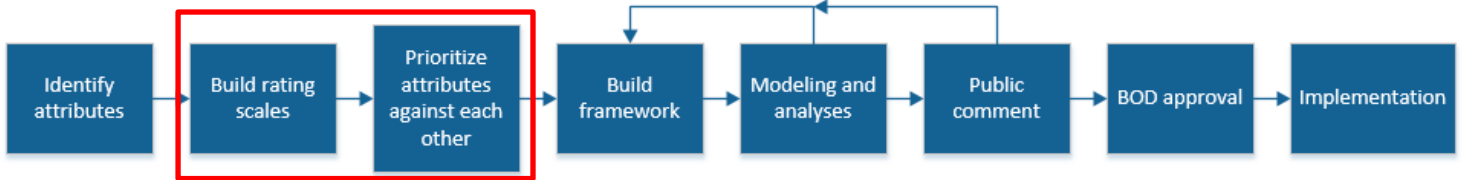
Relative Weights

Now that the Committee has a better sense of which attributes they would like to include in the first iteration of continuous distribution, their work will shift to deciding how much weight or relative importance each goal and attribute should have within the CAS. With input from the transplant community, the Committee must weigh the relative importance of each attribute against each other and determine how much importance each attribute should have in the overall CAS. For example, **Figure 6** below shows the weights assigned to each attribute and goal within the lung continuous distribution system. The Committee will utilize several different tools to determine the relative weight of each attribute in the CAS, including a values prioritization exercise, revealed preference analysis, and mathematical optimization. Each of these tools is described in more detail below.

Figure 6: Percent of Lung Composite Allocation Score (by Attribute)

Attribute	Weight
Waiting list Survival	25%
Post-Transplant Survival	25%
Candidate Biology	15%
Blood Type	5%
CPRA	5%
Height	5%
Patient Access	25%
Pediatric	20%
Prior Living Donor	5%
Placement Efficiency	10%
Travel Efficiency	5%
Proximity Efficiency	5%

Values Prioritization Exercise

As part of this public comment cycle, the transplant community is asked to participate in a structured values prioritization exercise. This exercise utilizes analytical hierarchy process (AHP) methodology to aid

in values-based decision-making.[14] AHP is a multi-criteria decision making methodology that asks participants a series of questions to compare the relative importance of a set of criteria through multiple pairwise comparisons.[15] The exercise asks participants for their opinion on how the different attributes or goals should be weighed against each other in a quantitative and systematic fashion.

While the Committee is utilizing more traditional analytical methods to build rating scales (more detail provided below), weighing attributes against each other is values laden rather than a clinical or operational question. For example, finding the proper balance between equity and utility is a frequent discussion amongst the OPTN committees when developing organ allocation policies and cannot be solved with traditional analytical methods or clinical input. Rather, such discussions are centered on the values of the Committee members and what they deem to be more important in the organ allocation system. The values prioritization exercise that is open for public participation is a structured way for the Committee to solicit feedback from the community on their priorities and what they value in the new allocation framework. A similar approach was utilized by the OPTN Lung, Kidney, and Pancreas Transplantation Committees.[16,17]

The values prioritization exercise shows each participant a series of pairwise comparisons of different attributes or goals that will be used to prioritize candidates. Participants will then be asked which attribute/goal is more important and how much more important is that attribute/goal than the other. Participants are also encouraged to leave comments to explain their rationale as this information is helpful to the Committee's deliberations. For example, **Figure 7** shows a sample pairwise comparison between two attributes in the values prioritization exercise.

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[14] OPTN, *Continuous Distribution,* Help build the framework. Available at https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/#CD_BuildTheFramework.

[15] *See generally*, Lin, Carol and Harris, Shannon 2013. A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study. Journal of Multi-Criteria Decision Analysis.

[16] *See generally* Mark, T. L., & Swait, J., 2004. Using stated preference and revealed preference modeling to evaluate prescribing decisions. Health economics.

[17] *See generally*, Lin, Carol and Harris, Shannon 2013. A Unified Framework for the Prioritization of Organ Transplant Patients: Analytic Hierarchy Process, Sensitivity, and Multifactor Robustness Study. Journal of Multi-Criteria Decision Analysis.

Figure 7: Sample Pairwise Comparison

The exercise will allow the Committee to see how the community ranks the attributes against each other and the community's preference for the weight of each attribute in the overall CAS. The Committee will review the results stratified by different demographic categories.

The Committee will review and discuss the differences between the baseline of current policies and the community's expressed priorities, along with a comparison against the OPTN's obligations in the NOTA and the OPTN Final Rule. While the results of the values prioritization exercise will reflect the opinion of the community, which is valuable information for the Committee moving forward, the Committee is not bound by the majority perspective of the prioritization exercise, as the Committee must put forward a proposal that meets OPTN statutory and regulatory requirements and reflects their clinical and professional expertise.

Revealed Preference Analysis

The Committee will also consider the results of a Revealed Preference Analysis (RPA) to approximate the weights of the attributes in current policy. The RPA, conducted in conjunction with the Research Triangle Institute (RTI), will approximate the relative weights for each attribute or goal that exists in the current allocation system, if nothing else changed, providing a baseline for the Committee to consider. The results of the RPA will give important insight into how the attributes and goals would be weighted if the Committee chose to mimic the current allocation system, to the extent possible, in the points-based framework. In reality, the Committee will likely choose weights that differ from the results of the RPA, as the Committee will have the ability to optimize certain outcomes beyond the current system and plan to include new attributes in the points-based framework. Nonetheless, the RPA will provide important insight into how the current system would look under a points-based allocation framework.

Optimization Analysis

In addition to the values prioritization exercise and RPA, the Committee also plans to collaborate with the Massachusetts Institute of Technology (MIT) on an optimization analysis exercise. Optimization analysis applies artificial intelligence and machine learning to the Organ Allocation Simulation (OASim) dataset to allow for optimization of specific outcomes.[18] For example, the OPTN Lung Transplantation Committee used the optimization analysis to choose a relative weight of 20 percent for pediatric priority, as the analysis showed that setting the weight for this attribute at 20 percent would likely achieve the desired transplant rate for the pediatric population and any increase in the weight above 20 percent was unlikely to have much impact on pediatric access to transplant.[19] The optimization analysis will allow the Committee to understand the relative weights they will need to consider for certain attributes in order to achieve a desired outcome.

Rating Scales

In addition to determining the relative weights of each attribute or goal, the Committee will also begin building the rating scales for each attribute. A rating scale is used to determine exactly how many points will be provided to each candidate based on their characteristics and the specific match run. For example, in a hypothetical example, if the Committee decides to weight proximity efficiency as 10 percent of the overall CAS, the rating scale for proximity efficiency will determine how many points out of the 10 percent each candidate will receive on the match run for proximity efficiency.

An example of how the Committee may build a rating scale for proximity efficiency is included below (**Figure 8**). This piecewise linear function is currently under consideration by the OPTN Kidney Transplantation Committee for the continuous distribution of kidneys.[20] There are four linear segments in this piecewise function. The first segment is the "inner plateau" which extends out to 50 nautical miles (NM) and prioritizes candidates registered at transplant programs located very closely to the donor hospital. The next segment, which is the "driving distance slope," has a slightly steeper slope than the inner plateau and is intended to still provide higher priority for candidates within a driving distance of the donor hospital. The shallow slope in this segment was incorporated to capture the fact that there is no major difference in cost, logistics, etc. between driving 100 NM or 249 NM, for example. Following the "driving distance slope" is the "driving/flying uncertainty zone," which runs from 250 NM out to 500 NM. This segment has a steeper slope as it covers the range of distances over which transplant programs will begin choosing to fly to procure the organ, representing a steep increase in costs. Beyond 500 NM, the final segment of the piecewise function slowly tapers out to 5,181 NM, reflecting the fact that organs will be flown beyond 500 NM but there is no major difference in costs once the decision is made to fly.

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[18] OASim is a computer simulation program developed by SRTR to simulate allocation of organs and outcomes of candidates on the waiting list and posttransplant

[19] OPTN Lung Transplantation Committee, *Briefing Paper,* Establish Continuous Distribution of Lungs. Public Comment Period August 3, 2021 – September 30, 2021. https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

[20] OPTN Kidney and Pancreas Transplantation Committees, *Committee Update*, Update on Continuous Distribution of Kidneys and Pancreata. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/ha2mpuor/continuous-distribution-of-kidneys-and-pancreata_comm-update_summer-2022.pdf.

Figure 8: Sample Proximity Efficiency Rating Scale
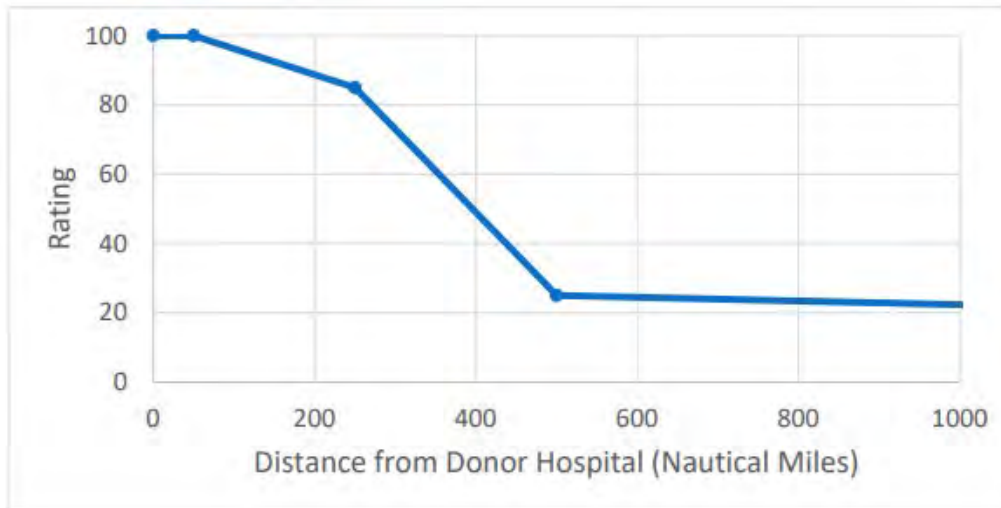
This represents just one example of a rating scale and the Committee will need to go through a similar exercise for each attribute they intend to include in the first iteration of continuous distribution. Some rating scales, such as pediatric priority or prior living donors, will be simple, binary functions. However, other attributes, such as population density or height/body surface area (BSA) will be more difficult. The Committee will use all available resources, relying heavily on traditional analytical methods and published research to develop rating scales for each attribute. Where possible, and in agreement with the Board's mandate for a more consistent organ allocation system, the Committee will utilize the analyses and precedents used in other continuous distribution proposals.

Progress To Date

Over the past twelve months, the Committee has identified and considered attributes related to liver and intestine allocation to be incorporated in the first iteration of continuous distribution. The previous concept paper described a list of attributes the Committee was initially considering.[21] Since the paper was released, the Committee has evaluated each potential attribute for inclusion in continuous distribution and narrowed the list of attributes they intend to include in the points-based framework.

The following sections describe the Committee's approach to evaluate each attribute and provide more detail on each potential attribute. The Committee is seeking public feedback on the proposed list of attributes to be included in the first iteration of continuous distribution.

In addition, many of the attributes includes below are also included in the values prioritization exercise. As members of the community complete the values prioritization exercise, they are encouraged to use this document as a resource when considering how to weight the different attributes and goals.

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[21] OPTN Liver and Intestinal Organ Transplantation Committee, Concept Paper, Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/fzmjii35/continuous-distribution-of-livers-and-intestines-concept-paper_liver_pc-summer-2022.pdf.

Attribute Review Approach

To determine which attributes to include in the first iteration of continuous distribution, the Committee undertook a structured review process that relied on available data, published literature, and subject matter experts.

First, as outlined in the previous concept paper, the Committee created a list of attributes that exist in the current policy for liver and intestines and a list of potential new attributes that do not exist in current policy but may align well with a points-based framework.[22] The Committee then focused on the potential new attributes and discussed which of these attributes should be included in the first iteration of continuous distribution.

For the new attributes, a subset of the Committee was assigned to review the available literature and data on the specific attribute and present an overview of this information to the full committee for further discussion and consideration. Subject matter experts were consulted as needed. This process was focused on determining which of the new attributes were ready for inclusion in the first iteration of continuous distribution. The conversation centered around the potential benefit of including the attribute weighed against the feasibility of including the attribute.

As a reminder, the primary goal of this overall project is to convert the current classification-based allocation system to a points-based framework, which will be a complicated process in and of itself. As such, the Committee considered new attributes only if they were well-supported by the available data, were likely to have a significant impact on the allocation system, and could be relatively easily incorporated into a points-based framework.

To help guide these conversations, the Committee focused on answering the following questions for each attribute:
- What solutions, if any, have already been developed?
    - *Utilizing a solution that has already been developed and vetted will be simpler and faster than the Committee developing a new solution.*
- Are there competing solutions to this problem?
    - *Topics that have clear consensus around a single solution will be easier to incorporate than topics where there are competing solutions.*
- What research exists to show this is an effective solution(s)?
    - *The Committee was specifically interested in solutions that have been demonstrated to effectively address the problem they intend to solve.*
- Is there community consensus on a solution?
    - *Solutions that already have community consensus on their effectiveness and feasibility will be easier to incorporate than solutions for which there is no consensus.*
- What would the committee need to do to develop a solution?
    - *If a solution did not already exist but the Committee was still interested in incorporating the attribute into continuous distribution, they weighed the time and resources needed to develop the solution against the value of the potential solution.*
- How complex are potential solutions?
    - *Transitioning from a classification-based framework to a points-based framework will be a complex effort in and of itself. Incorporating additional attributes that do not already*

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[22] Ibid.

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exist in allocation policy will increase the complexity of the project. As such, the Committee was interested in new attributes that will minimize the complexity of the overall project to the extent possible.

- Are there options that can be more easily incorporated than others?
  - *The Committee weighed the ease with which each new attribute and associated solution could be incorporated against the time and resources needed to incorporate the solution and its anticipated effectiveness. For some attributes, there were options that could be more easily incorporated than other options but not as effective. The Committee considered the effectiveness versus the anticipated complexity for each of these attributes and corresponding solutions.*

- How does the solution align with Final Rule, the NOTA, committee/community sentiment?
  - *All aspects of the new framework will need to align with the requirements outlined in the Final Rule and the NOTA. In addition, the Committee will continue to consider attributes that align with the values of the larger transplant community.*

- Does the OPTN currently collect necessary data? If not, what needs to be collected?
  - *The Committee considered if the data needed to incorporate each attribute is already collected by the OPTN. If the data was not already collected, the attribute was not further considered for the first iteration of continuous distribution. However, the Committee identified certain data elements that could be collected in order to implement future improvements to the allocation system.*

- Does this impact other organs?
  - *One benefit of utilizing a points-based framework is the ability for consistency across organs. The Committee considered any impact their proposed attributes/solutions may have on other organs. Where appropriate, the liver allocation system should align with the other allocation systems.*

- Would the attribute benefit from additional time and research before incorporating into liver allocation?
  - *The Committee considered if additional time and research are needed before incorporating a certain attribute or solution into the new allocation system.*

After reviewing and discussing each of the proposed new attributes, Committee members completed an informal poll asking them to rank the potential benefit and feasibility of incorporating the attribute into continuous distribution. Members completed this poll at the Committee's in-person meeting and the results were used to guide the Committee's discussion on which attributes should continue to be considered for inclusion in the first version of continuous distribution. [23]

The sections below include a summary of the Committee's discussion on each potential new attribute, as well as a list of initial attributes they plan to include in the first iteration of continuous distribution.

Attributes for Liver Allocation

Table 1 shows the list of attributes for the allocation of livers and their associated goal as developed by the Committee. Additional information on attributes that the Committee considered but did not decide to include in the first version of continuous distribution are detailed in a subsequent section.

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[23] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.

Importantly, this list of attributes is subject to change depending on community feedback, forthcoming literature, operational considerations, and modeling results.

Again, many of these attributes or their associated goal are included in the accompanying values prioritization exercise. As members of the community complete the values prioritization exercise, this document should serve as a reference, providing background on the Committee's deliberations to date.

Table 1: OPTN Liver & Intestinal Transplantation Committee Identified Attributes for Liver Allocation

	Medical Urgency	Post-Transplant Survival	Candidate Biology	Patient Access	Placement Efficiency
Attributes	• Status 1A/1B • MELD/PELD/ OPOM • Candidate Diagnosis points (Status 1B) • Liver-intestine registration		• Candidate blood type • Height/BSA	• Candidate Age • Waiting time • Liver-intestine registration • Prior living donor • Split liver transplant	• Travel Efficiency • Proximity Efficiency • Population density

Medical Urgency

The OPTN Final Rule calls for allocation policies to "seek to achieve the best use of donated organs."[24] One way to achieve the best use of a donated organ is to transplant the organ into a candidate who has the greatest medical urgency. Also, the Final Rule calls for the OPTN to "[set] priority rankings … for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent…"[25]

For the sake of simplicity, the following attributes are rolled into a single medical urgency category for the values prioritization exercise. For instance, the values prioritization exercise asks respondents to compare a highly-medically urgent candidate to other types of candidates but does not differentiate based on MELD, PELD, or urgency status. This will allow the Committee to understand how much medical urgency should be weighted in the new allocation system but still relies on the clinical differences between the medical urgency attributes to differentiate between candidates based on medical urgency.

Status 1A and Status 1B

In current policy, candidates listed as Status 1A receive the highest priority in liver allocation. These candidates have a life expectancy of less than seven days without a liver transplant. Status 1B is reserved for pediatric candidates with a higher need for transplant than other candidates with MELD or PELD scores. Candidates listed as Status 1B are typically offered organs after Status 1A candidates. The Committee intends to maintain the same priority in the points-based framework that these candidates receive in the current allocation system.

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[24] 42 CFR Sec. 121.8(a)(2).
[25] 42 CFR Sec. 121.8(b)(2).

While the Committee still needs to determine precisely how to incorporate these priority statuses into continuous distribution, they will likely be incorporated such that candidates meeting the criteria for each respective priority status will receive a certain number of medical urgency points within the CAS. The amount of medical urgency points will need to be sufficiently high to allow these candidates to be listed at or near the top of each match run, similar to their current priority.

During the Committee conversations related to re-transplant and surgical complexity (more detail on these topics is provided below), they expressed an interest in expanding the timeframe for candidates with hepatic artery thrombosis (HAT) to qualify for Status 1A. In current policy, in order for an adult candidate to qualify for Status 1A with HAT, they must meet the clinical criteria within 7 days of transplant. The Committee noted that it may be beneficial to lengthen this timeframe to 15-30 days post-transplant as part of the transition to continuous distribution.[26]

MELD, PELD, and OPOM

After the priority statuses, candidates are then ranked by decreasing MELD and PELD scores, which are calculations based on a number of clinical lab values that predict a candidate's likelihood of waitlist mortality within 90 days. In June 2022, the OPTN Board of Directors approved updates to the MELD and PELD calculations to better predict mortality and rank candidates on the liver waitlist. Most importantly, the updated MELD score, or MELD 3.0, includes a sex variable that will alleviate some of the sex-based disparity in the current liver allocation system for female candidates.[27] The updated MELD and PELD scores are tentatively slated to be implemented in the spring of 2023.

While MELD and PELD have been the foundation of liver allocation for more than 20 years, the Committee is also considering converting the medical urgency score used in liver allocation from MELD and PELD to the optimized predication of mortality or OPOM, which uses machine learning techniques to rank adult liver transplant candidates based on their medical urgency for transplant.[28] Proponents of OPOM contend that it more accurately ranks adult liver transplant candidates based on their risk of waitlist mortality and more effectively interdigitates candidates with hepatocellular carcinoma (HCC) into the scoring system than MELD does. The Committee was interested in continuing to consider OPOM as the medical urgency score in the continuous distribution system based on its potential to better rank adult candidates and reduce waitlist mortality.[29]

However, other Committee members remained concerned that changing to OPOM at the same time as continuous distribution would be too complicated and too complex to occur simultaneously. Members also noted concern with the fact that there is no corresponding OPOM score for pediatric candidates and highlighted the need for additional transparency and validation in the underlying methodologies used in the development of the OPOM score. Some Committee members also noted that the cohort used to develop the score is older and could benefit from a more recent cohort.[30]

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[26] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.
[27] OPTN Liver and Intestinal Organ Transplantation Committee, *Briefing Paper,* Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B. Public Comment Period January 27, 2022-March 27, 2022. https://optn.transplant.hrsa.gov/media/kxhdo0h4/improving-liver-allocation_meld-peld-status-1a-and-status-1b_winter-2022-pc.pdf.
[28] Dimitris Bertsimas et al., "Development and Validation of an Optimized Prediction of Mortality for Candidates Awaiting Liver Transplantation," *American Journal of Transplantation* 19, no. 4 (June 2018): pp. 1109-1118, https://doi.org/10.1111/ajt.15172.
[29] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.
[30] Ibid.

The Committee will continue to discuss the advantages and disadvantages of transitioning to OPOM as the acuity score used in continuous distribution.

The Committee is interested in the community's input on using OPOM in the continuous distribution of livers and intestines. Specifically, the Committee is interested in feedback from the community on if the Committee should update the medical urgency score used in allocation from MELD/PELD to OPOM concurrently with changing the entire allocation system to a points-based framework.

Candidate Diagnosis Points (Status 1B)

During their meeting in June 2022, the OPTN BOD approved a proposal to sort candidates within Status 1B based on diagnosis points.[31] These points will prioritize Status 1B candidates with chronic liver disease, who are at the highest risk of mortality, ahead of other Status 1B candidates. The Committee intends to keep this level of priority within Status 1B for candidates with chronic liver disease in the continuous distribution system. The Committee has not yet discussed exactly how these candidates will be prioritized but it will likely entail additional medical urgency points within the CAS for candidates meeting the criteria for Status 1B with chronic liver disease.

Liver-Intestine Registration

In current policy, adult candidates registered for an intestine as well as a liver automatically receive a 10 percent increase based the risk of 3-month mortality in their MELD score. Pediatric candidates listed for an intestine as well as a liver are provided 23 additional MELD or PELD points.[32] This additional priority reflects the fact that these candidates are more medically urgent than otherwise similar candidates who are only listed for a liver.[33,34] However, recent research has also demonstrated that the 10 percent increase based on risk of 3-month mortality may not be sufficient for some liver-intestine candidates.[35]

In addition, candidates registered for a liver-intestine receive priority for liver-intestine offers in the current allocation schema. Liver-intestine combinations are offered to all liver-intestine candidates across the nation, regardless of MELD or PELD score, before being offered to any liver-alone candidates with a MELD or PELD below 29.

The Committee intends to increase the level of priority for liver-intestine candidates in continuous distribution, based on their ongoing work to create NLRB guidance for multivisceral transplant (MVT) candidates.[36] This increased priority could include providing additional CAS points for liver-intestine candidates for all donors and/or providing additional CAS points for liver-intestine candidates for specific donors that meet the unique needs of liver-intestine candidates.

[31] Ibid.

[32] OPTN Policy 9.1.F: Liver-Intestine Candidates, as of December 2022.

[33] J Fryer, "Mortality in Candidates Waiting for Combined Liver-Intestine Transplants Exceeds That for Other Candidates Waiting for Liver Transplants," *Liver Transplantation* 9, no. 7 (2003): pp. 748-753, https://doi.org/10.1053/jlts.2003.50151.

[34] J. Kaplan et al., "The Impact of Meld/Peld Revisions on the Mortality of Liver-Intestine Transplantation Candidates," *American Journal of Transplantation* 11, no. 9 (September 2011): pp. 1896-1904, https://doi.org/10.1111/j.1600-6143.2011.03628.x.

[35] Tommy Ivanics et al. "Impact of the Acuity Circle Model for Liver Allocation on Multivisceral Transplant Candidates," American Journal of Transplantation 22, no. 2 (2021): pp. 464-473, https://doi.org/10.1111/ajt.16803.

[36] OPTN Liver and Intestinal Organ Transplantation Committee, *Public Comment Proposal,* National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates. Public Comment Period January 18, 2023 – March 15, 2023. Available at https://optn.transplant.hrsa.gov/

Post-Transplant Survival

The OPTN Final Rule calls for allocation policies "to avoid futile transplants."[37] Currently, the liver and intestine allocation system does not include a factor for post-transplant survival. However, other organs, namely kidney allocation, do account for post-transplant survival. Current kidney allocation includes a factor called Expected Post Transplant Survival (EPTS), which is used to predict a candidate's projected longevity with a functioning graft. The EPTS score works together with the Kidney Donor Profile Index (KDPI) of the donor kidney to match the organ to the appropriate candidate to maximize graft and patient survival.[38,39] Similarly, the policy for the continuous distribution of lungs includes an attribute that quantifies the expected number of days a candidate will live during the first five years post-transplant.[40]

The Committee held extensive conversations on including post-transplant survival in continuous distribution of liver and intestines but ultimately decided that there were no models readily available that would be easily incorporated and produce a sizable benefit to the allocation system. Therefore, the Committee has not included post-transplant survival in the list of attributes for the first iteration of continuous distribution.[41]

During their deliberations about post-transplant survival, the Committee reviewed a number of specific post-transplant models that already exist and, more generally, focused on two options as a means to address post-transplant survival: futility and utility.[42,43] Whereas utility is focused on maximizing the number of life years gained and longer term post-transplant outcomes, futility is focused on short-term post-transplant survival (60-90 days).[44]

The already-developed models for post-transplant survival in liver transplant are focused on longer-term outcomes (5 years post-transplant). These models intend to maximize utility by providing priority to candidates likely to survive for multiple years post-transplant. These models have c-statistics around 0.6, which means the models are moderately predictive and not consistently reliable. [45, 46, 47] In addition, the Committee was concerned that incorporating such models could inadvertently disadvantage certain

[37] 42 CFR §121.8(a)(5).

[38] OPTN Policy 8.5.A: Candidate Classifications

[39] OPTN Kidney Transplantation Committee. 2020, September 25. Kidney Continuous Distribution Workgroup Meeting Summary. https://optn.transplant.hrsa.gov/media/4128/20200925_kidney_continuousdistribution_wg_summary.pdf.

[40] OPTN Lung Transplantation Committee, *Briefing Paper,* Establish Continuous Distribution of Lungs. Public Comment Period August 3, 2021 – September 30, 2021. https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

[41] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 28, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.

[42] Goldberg D, Mantero A, Newcomb C, Delgado C, Forde KA, Kaplan DE, John B, Nuchovich N, Dominguez B, Emanuel E, Reese PP. 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.

[43] 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.

[44] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 28, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.

[45] Goldberg D, Mantero A, Newcomb C, Delgado C, Forde KA, Kaplan DE, John B, Nuchovich N, Dominguez B, Emanuel E, Reese PP. 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.

[46] 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.

[47] A c-statistic is a measure of how reliable a model predicts and outcome. Models with a c-statistic closer to 1 are more desirable as they are considered better at predicting outcomes. A c-statistic of 0.5 means the model is no better at predicting an outcome than random chance. A c-statistic of 1.0 means the model is perfect at predicting an outcome.

groups of candidates, such as older candidates, who may not be predicted to survive for a significant amount of time after transplant but still derive benefit from the procedure. Given the lack of statistical power in the models predicting longer term utility, the Committee decided not to include such an attribute in the continuous distribution system.[48]

The Committee also considered incorporating a futility threshold, which would categorize candidates based on clinical factors predicting the likelihood that the candidate will survive in the short term (60-90 days) post-transplant. In this example, candidates who do *not* meet the clinical criteria for the futility threshold would receive additional CAS points, whereas candidates who do meet the criteria, would not receive the points. In effect, the threshold would deprioritize candidates who have an increased chance of mortality or graft loss in the 60 to 90 days after transplant.

However, the Committee ultimately decided not to include a futility threshold for two reasons. First, transplant programs are unlikely to pursue futile transplants, as the Scientific Registry of Transplant Recipients (SRTR) monitors transplant programs based on post-transplant outcomes. The Committee agreed that adding a futility threshold into OPTN policy was not expected to have an impact on avoiding futile transplants, as programs already avoid such procedures due to SRTR monitoring. Second, the Commttee noted that each candidate's clinical team is more likely to understand the candidate's likelihood of a futile transplant than a formula-driven policy is able to predict such an event.[49]

For these reasons, the Committee decided not to include post-transplant survival as an attribute in the first iteration of continuous distribution of livers and intestines. The Committee is interested in public feedback on their decision to not include a factor for post-transplant survival in the continuous distribution system.

Candidate Biology

The NOTA requires the OPTN to consider candidates "whose immune system makes it difficult for them to receive organs,"[50] and the OPTN Final Rule calls for allocation policies to "promote patient access to transplantation."[51] Some candidates have difficulty finding a suitable donor due to biological incompatibilities and the OPTN has long used different mechanisms such as Calculated Panel Reactive Antibody (CPRA) in kidney allocation and prioritizing candidates with specific blood types for certain donors to equalize access to transplant for biologically disadvantaged candidates. The Committee has identified candidate blood type and height/body surface area (BSA) as the two attributes to be included in continuous distribution related to candidate biology.

In the values prioritization exercise, the following attributes were combined into a single candidate profile. The values prioritization exercise asks respondents to weight the importance of prioritizing a biologically difficult to match candidate. This will give the Committee insight into how much to weight candidate biology but still allows for clinical differentiation based on blood type and height/BSA.

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[48] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 28, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/.
[49] Ibid.
[50] 42 U.S.C. §274(b)(2)(A)(ii)
[51] 42 CFR §121.8(a)(5).

Candidate blood type

In the current allocation system, candidates with blood type O and blood type B are provided additional priority for blood type O donors. This prioritization is intended to improve access to transplant for a population of candidates who, due to their specific biology, are expected to have a more difficult time accessing transplant.[52] The current allocation policy also sorts candidates within a classification based on their blood type compatibility with the donor. Within a given classification, if multiple MELD/PELD scores are equal, candidates with an identical blood type are ranked ahead of candidates with a compatible blood type who are then ranked ahead of candidates with an incompatible blood type.[53]

The Committee has not specifically discussed how to construct the rating scale for blood type compatibility yet, but will build upon the work already done for lung, kidney, and pancreas to incorporate blood type into the new system.

The OPTN Lung Transplantation Committee created a rating scale for biological disadvantages which includes blood type, CPRA, and height. The specific blood type rating scale is based on the proportion of donors incompatible with a candidates based on the candidate's blood type. This proportion is then aligned with the biological disadvantages rating scale.[54] In this way, the Lung Committee used clinical evidence to construct the rating scales and weight these three attributes. The OPTN Kidney and Pancreas Transplantation Committees are considering different options that will maintain screening for blood type O and B for kidney allocation or prioritization of identical over compatible blood type matches in addition to a rating scale for blood type.[55] The Committee will consider the work already done for lung, kidney, and pancreas when developing the rating scale for blood type.

Height or Body Surface Area (BSA)

Height or BSA as an attribute in continuous distribution intends to address the inherent biological disadvantages that affect liver transplant candidates of shorter stature. Published research has consistently documented that liver transplant candidates who are shorter have reduced access to transplant, as many livers from larger donors are not size-appropriate.[56,57,58] Put more simply, if two candidates have the same MELD score, the shorter candidate will likely have a more difficult time finding a size appropriate donor. In fact, while developing MELD 3.0, the Committee strongly considered including a factor for candidate height, but data suggested that height is more correlated to reduced access to transplant, as opposed to risk of waitlist mortality.[59]

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[52] OPTN Liver and Intestinal Organ Transplantation Committee, *Briefing Paper*, Liver and Intestine Allocation Using Distance from Donor Hospital. Public Comment Period October 8, 2018-November 1, 2018. Available at https://optn.hrsa.gov.

[53] OPTN Policy 9.8.D: Sorting Within Each Classification

[54] OPTN Lung Transplantation Committee, *Briefing Paper,* Establish Continuous Distribution of Lungs. Public Comment Period August 3, 2021 – September 30, 2021. https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.

[55] OPTN Kidney and Pancreas Transplantation Committees, *Committee Update*, Update on Continuous Distribution of Kidneys and Pancreata. Public Comment Period August 3, 2022 – September 28, 2022. https://optn.transplant.hrsa.gov/media/ha2mpuor/continuous-distribution-of-kidneys-and-pancreata_comm-update_summer-2022.pdf.

[56] J. C. Lai et al., "Height Contributes to the Gender Difference in Wait-List Mortality under the Meld-Based Liver Allocation System," *American Journal of Transplantation* 10, no. 12 (2010): pp. 2658-2664, https://doi.org/10.1111/j.1600-6143.2010.03326.x.

[57] Alina M. Allen et al., "Reduced Access to Liver Transplantation in Women," Transplantation 102, no. 10 (October 2018): 1710–16, https://doi.org/10.1097/tp.0000000000002196.

[58] Jin Ge and Jennifer C. Lai, "Identifying a Clinically Relevant Cutoff for Height That Is Associated with a Higher Risk of Waitlist Mortality in Liver Transplant Candidates," *American Journal of Transplantation* 20, no. 3 (April 2019): pp. 852-854, https://doi.org/10.1111/ajt.15644.

[59] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* August 27, 2021.

The Committee reviewed a number of published models for addressing the difficulty faced by shorter stature candidates in accessing transplant.[60] The Committee preferred models that would increase the priority of the lowest BSA candidates for low BSA donors.[61,62] The Committee preferred this model for two reasons. First, BSA is expected to be more correlated with anteroposterior (AP) diameter than height.[63] Secondly, whereas height only incorporates one dimension, BSA incorporates three dimensions, which is also how livers grow. BSA is known to correlate well with liver volume in donors.[64] For these reasons, the Committee preferred a BSA-based model over a model based purely on candidate height.

In addition, research has demonstrated that even when ranked first on a match run, the likelihood of a decline was higher for female candidates, who tend to be of smaller stature, than male candidates.[65] As such, the Committee noted that simply providing additional points to candidates under a certain height may not have the desired effect of increasing access to transplant for candidates of shorter stature. In fact, doing so may slow down the allocation process, as many offers are unlikely to be accepted for these candidates. Therefore, the Committee generally preferred an approach whereby candidates with a lower BSA would be provided priority only for donors also with a lower BSA.[66] Within continuous distribution, this would entail providing additional candidate biology points to low BSA candidates for low BSA donors.

If included in the final proposal, this attribute would have a larger impact on certain disadvantaged groups, such as Hispanic and Asian candidates, pediatric candidates, and female candidates. Public comment supported the inclusion of an attribute to address size mismatch.[67] Additionally, inclusion of this attribute aligns with the recent National Academies of Science, Engineering, and Medicine (NASEM) recommendation to "include a modifier based on body size or muscle mass to overcome the demonstrated disparities observed for patients of smaller size".[68]

The Committee is seeking public feedback on the inclusion of height or BSA as an attribute in continuous distribution.

Patient Access

The OPTN Final Rule requires allocation policies to "promote patient access to transplantation,"[69] and the NOTA requires the OPTN to "recognize the differences in health and in organ transplantation issues

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[60] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* September 30, 2022. https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/

[61] Ibid.

[62] More information on BSA and how it is calculated can be found here: https://www.nursingcenter.com/ncblog/august-2017/body-mass-index-and-body-surface-area-what-s-the-d

[63] Madhur Gupta, Lavina Sodhi, and T. D. Yadav, "Morphology of Liver," *Indian Journal of Surgery* 70, no. 1 (2008): pp. 3-7, https://doi.org/10.1007/s12262-008-0001-4.

[64] Koichi Urata et al., "Calculation of Child and Adult Standard Liver Volume for Liver Transplantation," *Hepatology* 21, no. 5 (1995): pp. 1317-1321, https://doi.org/10.1002/hep.1840210515.

[65] Lauren D. Nephew et al., "Exception Points and Body Size Contribute to Gender Disparity in Liver Transplantation," *Clinical Gastroenterology and Hepatology* 15, no. 8 (2017), https://doi.org/10.1016/j.cgh.2017.02.033.

[66] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 28, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/

[67] OPTN Liver and Intestinal Organ Transplantation Committee, *Concept Paper,* Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022.

[68] National Academies of Sciences, Engineering, and Medicine. 2022. Realizing the promise of equity in the organ transplantation system. Washington, DC: The National Academies Press. https://doi.org/10.17226/26364.

[69] 42 CFR §121.8(a)(5).

between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children."[70] Accordingly, the patient access goal is intended to ensure appropriate access to transplant for all transplant candidates. The Committee has identified candidate age, waiting time, liver-intestine registration, prior living donor, and split liver as the attributes to be included in continuous distribution related to patient access.

Candidate age

There are a number of instances where the current liver and intestine allocation system addresses the unique needs of the pediatric population. This includes areas such as the pediatric-specific criteria for Status 1A, the creation of Status 1B priority (which is reserved for pediatric candidates), assignment of higher exception scores for pediatric candidates, the prioritization of pediatric candidates for pediatric donors, and sorting pediatric candidates ahead of adults when MELD or PELD and blood type compatibility are equal.[71] These pediatric-specific policies reflect the unique clinical needs of the pediatric population and are in alignment with the OPTN White Paper titled "Ethical Principles of Pediatric Organ Allocation".[72]

Public comment was supportive of maintaining candidate age as an attribute in a points-based allocation system.[73] The Committee will continue to collaborate with pediatric stakeholders to ensure pediatric candidates are appropriately considered and provided sufficient priority and access to transplant.

Waiting time

In current liver allocation, waiting time is used in certain circumstances to sort candidates when other factors are equal. For instance, when candidates with a calculated MELD or PELD score are in the same classification, have the same MELD or PELD score, have the same blood type compatibility with the donor, and are in the same age category (pediatric vs. adult), they are then ranked based on time at their current MELD or PELD score or higher. Exception candidates are sorted similarly, except they are further ranked by time since submission of earliest approved exception. In effect, waiting time is used to prioritize the candidates who have been on the waiting list longer, when all else is equal. The Committee has not yet discussed how waiting time should be incorporated into continuous distribution but it is anticipated to play a similar role in continuous distribution as it does in current allocation policy, where it is primarily used as a tiebreaker when all else is equal.

Liver-intestine registration

Liver-intestine registration was also included as an attribute in the medical urgency goal described above. The Committee decided to also include it in the patient access goal because liver-intestine candidates need access to higher quality donors where the liver, intestine, pancreas, and sometimes kidney are available for transplant in addition to having higher waitlist mortality than liver-alone

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[70] 42 U.S.C. §274(b)(2)(M)

[71] This is not an exhaustive list of all areas where pediatric candidates are treated differently than adult candidates within OPTN Policy.

[72] OPTN, *Ethical Considerations,* Ethical principles of pediatric organ allocation. Updated November 2014. Available at https://optn.transplant.hrsa.gov/.

[73] OPTN Liver and Intestinal Organ Transplantation Committee, *Concept Paper,* Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022.

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candidates.[74] Recent research has also shown that liver-intestine candidates have lower transplant probability after the implementation of the acuity circles (AC) policy.[75] Therefore, the Committee has discussed providing points for candidates registered for a liver-intestine combination in both the medical urgency and patient access goals to reflect their higher medical urgency and need for better access to high quality donors.

As noted previously, the Committee plans to consider providing additional priority for liver-intestine candidates generally and also for specific donors.[76] The Committee is interested in community feedback on how liver-intestine candidates should be prioritized in continuous distribution.

Prior living donor

While prior living donors are not provided any additional priority in the current liver allocation system, the Committee recommends including this attribute in continuous distribution.[77] Public comment was supportive of this addition and notably the OPTN Ethics and Living Donor Committees have provided a framework and recommendations on how to include prior living donor priority into continuous distribution. [78,79,80] Further, there are both ethical and legal justifications for providing a form of priority for prior living donors.[81] The continuous distribution of lungs includes additional points for prior living donors, regardless of which organ the candidate previously donated, and the kidney and pancreas continuous distribution frameworks intend to do the same. The Committee plans to include some form of priority for prior living donors in the continuous distribution system.

Willingness to accept a split liver segment

A split liver transplant occurs when a transplant program accepts a donor liver and decides to split the liver into two segments, thereby transplanting two candidates from one donor organ. Split liver transplantation has the potential to have a substantial impact on access to liver transplant, particularly for pediatric candidates and small stature adults.[82] Yet, split liver transplantation remains an underutilized avenue to increase the number of transplants.[83]

While split liver transplant has historically been associated with higher risk of graft loss, recent research has demonstrated equivalent outcomes to living donor transplantation in children, and to whole graft

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[74] Tommy Ivanics et al., "Impact of the Acuity Circle Model for Liver Allocation on Multivisceral Transplant Candidates," *American Journal of Transplantation* 22, no. 2 (2021): pp. 464-473, https://doi.org/10.1111/ajt.16803.
[75] Ibid.
[76] OPTN Liver and Intestinal Organ Transplantation Committee, *Public Comment Proposal,* National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates. Public Comment Period January 18, 2023 – March 15, 2023. Available at https://optn.transplant.hrsa.gov/
[77] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/
[78] OPTN Liver and Intestinal Organ Transplantation Committee, *Concept Paper,* Continuous Distribution of Livers and Intestines Concept Paper. Public Comment Period August 3, 2022 – September 28, 2022. Available at https://optn.transplant.hrsa.gov/
[79] OPTN Ethics Committee, *Meeting Summary,* March 11, 2021. Available at https://optn.transplant.hrsa.gov/
[80] OPTN Living Donor Committee, *Meeting Summary,* May 12, 2021. Available at https://optn.transplant.hrsa.gov/
[81] OPTN Lung Transplantation Committee, *Briefing Paper,* Establish Continuous Distribution of Lungs. Public Comment Period August 3, 2021 – September 30, 2021. https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf.
[82] Mary G. Bowring et al., "Survival Benefit of Split-Liver Transplantation for Pediatric and Adult Candidates," *Liver Transplantation* 28, no. 6 (March 2022): pp. 969-982, https://doi.org/10.1002/lt.26393.
[83] Perito, E. R., Roll, G., Dodge, J. L., Rhee, S., & Roberts, J. P. (2019). Split Liver Transplantation and Pediatric Waitlist Mortality in the United States: Potential for Improvement. *Transplantation*, *103*(3), 552–557. https://doi.org/10.1097/TP.0000000000002249

deceased donor transplant in adults receiving extended right lobe grafts.[84,85] In addition, discard of liver segments that are otherwise acceptable for transplant remains high, further highlighting the opportunity for split liver transplantation to increase the number of transplants.

Based on this information and the potential for split liver transplantation to significantly increase access to transplant, particularly for disadvantaged populations, the Committee intends to incorporate an attribute aimed at increasing split liver transplantation in the continuous distribution system.[86]

More specifically, the Committee intends to explore a model that would trigger a unique match run for donors meeting "splittable" criteria that would include additional priority for those candidates likely to accept a split liver transplant (pediatric candidates under 7 kilograms (kg) or under age 2 and small adults).[87] The Committee will also explore using a second match run, as opposed to the same adult deceased donor match run, to allocate the second segment. This second match run could include an increased weight for proximity, which would make it more likely the second segment is offered and accepted at the same transplant program or a nearby transplant program, reducing logistical and efficiency-related barriers.[88]

The Committee is interested in public feedback on how the continuous distribution allocation system could increase the number of split liver transplants.

Placement Efficiency

The OPTN Final Rule does not define the "efficient management of organ placement." [89] However, a Federal Register notice related to the development of the OPTN Final Rule can provide some guidance for interpreting this clause. It states:

> Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient.[90]

The placement efficiency goal encompasses the amount of resources required to identify a suitable candidate willing to accept the organ and deliver the organ for transplant.

Placement efficiency is factored into the current liver and intestine allocation system by using concentric circles and prioritizing candidates closer to the donor hospital when other factors are similar. However, the Committee has an opportunity to consider the impact of placement efficiency in a more nuanced manner within continuous distribution.

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[84] Montgomery, J. R., Highet, A., Brown, C. S., Waits, S. A., Englesbe, M. J., & Sonnenday, C. J. (2022). Graft Survival and Segment Discards Among Split-Liver and Reduced-Size Transplantations in the United States From 2008 to 2018. *Liver transplantation : official publication of the American Association for the Study of Liver Diseases and the International Liver Transplantation Society*, *28*(2), 247–256. https://doi.org/10.1002/lt.26271

[85] Vladimir J. Lozanovski et al., "Outcome of Extended Right Lobe Liver Transplantations," *Liver Transplantation* 28, no. 5 (2021): pp. 807-818, https://doi.org/10.1002/lt.26374.

[86] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/about/committees/liver-intestinal-organ-transplantation-committee/

[87] OPTN Policy 9.8.A outlines the current criteria for livers that can be split. Available at https://optn.transplant.hrsa.gov

[88] Ibid.

[89] 42 CFR §121.8(a)(2).

[90] 63 FR 16315 (1998).

That being said, it is important to reiterate that the goal of continuous distribution is smarter distribution, not broader distribution of livers and intestines. The intent of continuous distribution is to remove the hard boundaries between classifications that exist in the current allocation system, such as the use of concentric circles. Removing these concentric circles does not necessarily mean that continuous distribution will result in livers and intestines being allocated over larger areas for all donors and candidates; instead, continuous distribution should permit broader access for the most urgent candidates and more localized allocation for organs that cannot travel as far. The transition to a points-based framework allows the Committee and the community to consider the impact of placement efficiency with more precision and nuance.

Travel efficiency

Flying represents a significant increase in costs of transportation for a transplant, and increased costs make the process less efficient. In general, travel distance impacts travel time; the farther an organ is transported, the more likely it is to travel by air than ground; and air travel is more expensive than ground travel for the same distance.[91,92] And finally, financial costs are only one aspect of overall placement system efficiency.

Even though the current circle sizes used in allocation were selected based on the available data and clinical input of the Committee, there remains opportunity to improve the way that travel is considered within the allocation of livers and intestines. Continuous distribution will allow the Committee to construct a rating scale for travel efficiency that better reflects the costs associated with organ procurement and transplantation, similar to the kidney example provided above.

The Committee has not yet determined how to incorporate travel efficiency into the continuous distribution of livers and intestines but will build upon the work already done for lung, kidney, and pancreas.

The Committee is interested in community feedback on the best way to incorporate travel efficiency into continuous distribution.

Proximity efficiency

Travel efficiency, or cost, is only one relevant aspect of placement efficiency, however. Importantly, geographic proximity (e.g., distance between donor and transplant candidate's hospital) may be considered to the extent necessary to satisfy requirements in the Final Rule: e.g., efficient management of organ placement and the avoidance of futile transplants due to increased ischemic time.[93] The proximity efficiency attribute measures the efficiency of transporting livers shorter distances other than decreased transportation costs. These include differences such as the time in transit for transplant teams, additional effort required to coordinate longer travel, and differences in the chance of something going wrong in transit the farther the personnel and liver/intestine must travel.

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[91] S. Gentry, E. Chow, N. Dzebisashvili, et al. The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients. Am J Transplant. 2016; 16(2):583-93

[92] Dubay DA, Maclennan PA, Reed RD, et al. The impact of proposed changes in liver allocation policy on cold ischemia times and organ transportation costs. Am J Transplant. 2015; 15(2):541-6

[93] 42 C.F.R. §121.8(a)(8)

Similar to travel efficiency, the Committee has not yet determined the rating scale for proximity efficiency but will build upon the work already done for the other organs when developing the rating scale and is interested in public feedback on the attribute.

Population Density

Population density impacts travel practices and varies across the country. The Committee intends to consider options to account for differences in population density within the context of placement efficiency. For example, within a given distance, organs recovered in dense, metropolitan areas can reach more candidates than organs recovered in less dense, rural areas. Related, travel in dense urban areas requires different resources than in less dense rural areas. The incorporation of population density will allow the continuous distribution model to better account for variability in travel practices across the country.

Some members have also suggested that a population density attribute will benefit geographic equity. The committee will continue to monitor the transplant system for geographic differences in access to transplant.

The Committee is seeking community feedback on the best ways to incorporate population density into a points based framework.

Attributes considered but not included

As previously noted, throughout the attribute review process, the Committee was particularly focused on including attributes that they anticipate to have a significant benefit while also being more easily incorporated into continuous distribution. Transitioning the current system into a points-based framework will be extremely challenging alone, and therefore, in the attribute review process, the Committee was careful not to include attributes that would significantly increase the complexity of the project with minimal anticipated benefit.

As a result, the Committee is not able to incorporate every proposed new attribute in the new allocation system. Any attempt to do so would be far beyond the scope of this project and delay the immediate benefits of transitioning to a continuous distribution framework. The sections below outline the attributes the Committee considered but decided not to include in the first iteration of continuous distribution. While the Committee recognizes that the attributes detailed below are important, there was consensus that these attributes are not currently feasible to incorporate into the first iteration of continuous distribution. The Committee seeks to continually reevaluate the identified attributes below for future iterations of continuous distribution.

Frailty

Sarcopenia and frailty are common complications in patients suffering from end-stage liver disease.[94] These complications are associated with increased risk of mortality and can impact a candidate's ability

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[94] Yedidya Saiman and Marina Serper, "Frailty and Sarcopenia in Patients Pre– and Post–Liver Transplant," *Clinics in Liver Disease* 25, no. 1 (2021): pp. 35-51, https://doi.org/10.1016/j.cld.2020.08.004.

to access transplant. On the other hand, these complications are also associated with adverse post-transplant outcomes and can be difficult to measure objectively.[95,96]

Due to the subjective measurement techniques, the Committee was concerned that incorporating frailty would allow for potential manipulation of a candidate's CAS.[97] There was also not consensus among the Committee whether frailty should be factored into waitlist mortality, post-transplant outcomes, or both. Notably, the OPTN does not collect the necessary data needed to analyze frailty.[98]

The Committee decided that while this attribute may be beneficial, the feasibility of incorporating it into the first iteration of continuous distribution was low.[99] The Committee seeks to continue to review measures such as the six-minute walk and liver frailty index for future versions of continuous distribution, and plans to recommend necessary data collection in the interim.[100]

Surgical complexity and re-transplant

The Committee noted that candidates who have already received a liver transplant and are subsequently re-listed for transplant are more difficult to transplant surgically and therefore have a more difficult time finding a suitable donor organ due to technical considerations.[101] The Committee also recognized that the anticipated surgical complexity of a transplant can dictate organ offer acceptance practices and post-transplant outcomes.

However, during their discussions on surgical complexity and re-transplant as a potential attribute in continuous distribution, the Committee agreed that there is little data to support additional priority for surgically complex candidates and prioritizing such candidates may actually portend worse post-transplant outcomes. The Committee also agreed that the expedited access to transplant for candidates with HAT, primary non-function, ischemic cholangiopathy, small-for-size syndrome and other acute post-transplant complications should be maintained in the new allocation system.[102, 103, 104] However, there is no evidence to support expanding this expedited access to other re-transplant candidates. The Committee upholds that continuous distribution should continue these expedited pathways, but a standalone attribute is not needed.[105]

HCC Stratification

Currently, HCC candidates meeting specific criteria in OPTN policy are provided a MELD or PELD exception score. After a six month delay, adult HCC candidates are assigned an exception score equal to

[95] Elizabeth J. Carey et al., "A Multicenter Study to Define Sarcopenia in Patients with End-Stage Liver Disease," Liver Transplantation 23, no. 5 (2017): pp. 625-633, https://doi.org/10.1002/lt.24750.

[96] Ching-Sheng Hsu and Jia-Horng Kao, "Sarcopenia and Chronic Liver Diseases," Expert Review of Gastroenterology & Hepatology 12, no. 12 (2018): pp. 1229-1244, https://doi.org/10.1080/17474124.2018.1534586.

[97] OPTN Liver and Intestinal Organ Transplantation Committee, Meeting Summary, October 11, 2022. Available at https://optn.transplant.hrsa.gov/

[98] Ibid.

[99] Ibid.

[100] Ibid.

[101] P.S. Yoo et al., "Retransplantation of the Liver: Review of Current Literature for Decision Making and Technical Considerations," Transplantation Proceedings 45, no. 3 (2013): pp. 854-859, https://doi.org/10.1016/j.transproceed.2013.02.063.

[102] Policy 9.1: Status and Score Assignments, as of December 2022.

[103] Policy 9.5: Specific Standardized MELD or PELD Score Exceptions, as of December 2022.

[104] OPTN Liver and Intestinal Organ Transplantation Committee, Meeting Summary, October 11, 2022.

[105] Ibid.

medium MELD at transplant (MMaT) minus three. Pediatric and adolescent HCC candidates are assigned a score equal to MELD or PELD 40. Current literature indicates that this population has variable risk of waitlist dropout and overall transplant benefit, based on factors including tumor burden, size, alpha-fetoprotein, and the severity of liver disease.[106,107] However, the same scores are assigned regardless of differences in these clinical factors in the current policy.

The Committee considered a number of models for better stratifying HCC candidates based on the relevant clinical factors in the new allocation system.[108,109,110,111] In the discussions specifically focused on HCC stratification, the Committee preferred a model that included a stratification of HCC candidates into distinct categories based on the relevant clinical factors to better align with their need for transplant.

However, the Committee decided to table HCC stratification as a potential new attribute because OPOM, which is described above, incorporates HCC candidates into the overall medical urgency score, removing the need for a separate HCC stratification attribute.[112] If the Committee decides to maintain the MELD and PELD scores, they may need to reconsider including HCC stratification in the first iteration of continuous distribution.

Candidate Social Determinants of Health[113]

The United States Department of Health and Human Services defines the social determinants of health as, "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."[114] Within the context of liver and intestine allocation, the social determinants of health have been demonstrated to play a role across the transplant process. Factors such as age, sex, race/ethnicity, insurance/socioeconomic status, and geography have all been shown to impact candidate access to transplant, waitlist outcomes, and post-transplant survival.[115]

While social determinants of health are important predictors of overall health status, the Committee did not think they should be a factor in liver allocation, primarily due to existing constraints on how to appropriately categorize candidates on the waitlist. The OPTN does not currently collect comprehensive candidate-level data on the social determinants of health and existing metrics for measuring the social

[106] Allison J. Kwong, T. Tara Ghaziani, and Neil Mehta, "Decreased Urgency among Liver Transplantation Candidates with Hepatocellular Carcinoma in the United States," *Liver Transplantation* 28, no. 4 (2021): pp. 725-727, https://doi.org/10.1002/lt.26373.

[107] Neil Mehta et al., "Predictors of Low Risk for Dropout from the Liver Transplant Waiting List for Hepatocellular Carcinoma in Long Wait Time Regions: Implications for Organ Allocation," *American Journal of Transplantation* 19, no. 8 (May 2019): pp. 2210-2218, https://doi.org/10.1111/ajt.15353.

[108] Mehta N, Dodge JL, Roberts JP, Yao FY. A novel waitlist dropout score for hepatocellular carcinoma - identifying a threshold that predicts worse post-transplant survival. *J Hepatol.* 2021;74(4):829-837. doi:10.1016/j.jhep.2020.10.033

[109] Toso C, Dupuis-Lozeron E, Majno P, et al. A model for dropout assessment of candidates with or without hepatocellular carcinoma on a common liver transplant waiting list. *Hepatology.* 2012;56(1):149-156. doi:10.1002/hep.25603

[110] Vitale A, Volk ML, De Feo TM, et al. A method for establishing allocation equity among patients with and without hepatocellular carcinoma on a common liver transplant waiting list. *Journal of Hepatology.* 2014;60(2):290-297. doi:10.1016/j.jhep.2013.10.010

[111] Marvin MR, Ferguson N, Cannon RM, Jones CM, Brock GN. MELD $_{EQ}$: An alternative Model for End-Stage Liver Disease score for patients with hepatocellular carcinoma: HCC-MELD-AFP Interaction. *Liver Transpl.* 2015;21(5):612-622. doi:10.1002/lt.24098

[112] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022.

[113] 42 C.F.R. §121.4(a)(3) permits the OPTN to develop "Policies that reduce inequities resulting from socioeconomic status, including…(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;"

[114] See https://health.gov/healthypeople/objectives-and-data/ social-determinants-health.

[115] Nabeel A. Wahid, Russell Rosenblatt, and Robert S. Brown, "A Review of the Current State of Liver Transplantation Disparities," *Liver Transplantation* 27, no. 3 (2021): pp. 434-443, https://doi.org/10.1002/lt.25964.

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determinants of health are all based on aggregate level indices. The correlation between the aggregate level metrics and specific candidates remains unknown and the Committee does not recommend incorporation of a factor into organ allocation using an aggregate-level metric with an unclear correlation to specific candidates.[116] The Committee suggests a larger OPTN effort to 1) collect candidate data related to the social determinants of health, particularly candidate address, in order to better understand individual candidate's social determinants of health and 2) consider how the OPTN can use this information to make organ transplantation more equitable for all transplant candidates.[117]

Other Considerations

In addition to the attribute discussions included above, the Committee has discussed or plans to discuss other important factors related to the continuous distribution of livers and intestines as described below.

Donor modifiers

In current allocation policy, there are distinct match runs based on donor age, donation after circulatory death (DCD) status, and if the organ procurement organization (OPO) is offering an intestine with the liver.

Specifically, pediatric candidates are provided priority for pediatric donors. Livers from donors over age 70 or DCD donors are offered to more proximate candidates reflecting the fact that these organs are generally considered more marginal organs and cannot withstand extended cold ischemia time. As noted previously, liver-intestine candidates are provided priority when the OPO is offering the liver with the intestine.

The Committee intends to continue to provide pediatric priority for pediatric donors and priority for liver-intestine candidates when a liver and intestine are available. They have not had detailed discussions about these donor modifiers yet, but plan to incorporate them into the new allocation framework.

The Committee has, however, spent time discussing donor quality, which is related to DCD donors and donors over age 70. Specifically, the Committee discussed if they should consider incorporating a continuous donor quality scale, similar to KDPI for kidneys, to better capture donor quality and allocate organs more effectively based on the quality of the donated organs.[118] The Committee reviewed potential models for measuring donor quality that are available in the literature and discussed if such scales should be incorporated into the first iteration of continuous distribution.[119]

The Committee considered different ways in which a continuous donor quality index could be incorporated into allocation policy including creating categories of donors, similar to KDPI, and prioritizing certain types of candidates for each category of donor. They also discussed a more simple option that would flag organs from donors below a certain donor quality score and prioritize these

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[116] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022. Available at https://optn.transplant.hrsa.gov/
[117] Ibid.
[118] Asrani, S., Saracino, G., Wall, A., et al. Assessment of donor quality and risk of graft failure after liver transplantation: The ID2 EAL score. Am J Transplant. 2022 Sep 2. doi: 10.1111/ajt.17191.
[119] OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary,* October 11, 2022.

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organs for healthier and more proximate candidates. However, the Committee noted that this might not have more benefit than using the same donor quality stratifications (DCD and age over 70) in the current allocation policy. [120]

The Committee will continue to consider how to incorporate donor quality into the first iteration of continuous distribution and is interested in community feedback on the topic.

In addition to these donor modifiers, the Committee will also consider donor modifiers based on height/BSA of the donor and for donors meeting "splittable" criteria, as described previously.

Intestine Attributes

Most of the Committee discussion thus far has been focused on liver-alone and liver-intestine allocation but the Committee will also need to consider how to convert intestine-alone allocation into a points-based framework. Luckily, intestine-alone allocation is simpler than liver-alone and liver-intestine allocation and the overall waitlist and number of intestine-alone transplants is significantly smaller than liver-alone and liver-intestine. Because intestine-alone allocation is simpler and balances fewer competing attributes, the values prioritization exercise focuses specifically on liver-alone and liver-intestine allocation. The Committee will utilize other analytical techniques to develop weights for intestine-alone allocation.

Intestine-alone candidates are stratified into three medical urgency statuses, with Status 1 being the most urgent, Status 2 being reserved for any candidates not meeting the criteria for Status 1, and the final status is for inactive candidates. In order to qualify for Status 1, a candidate must demonstrate any of the following:

- Liver function test abnormalities
- No vascular access through the subclavian, jugular, or femoral veins for intravenous feeding
- Medical indications that warrant intestinal organ transplantation on an urgent basis

In addition to the Status assignments, intestine candidates are also ranked based on their blood type compatibility with the donor, distance from the donor hospital, and waiting time. **Table 3** below lists the attributes for intestine allocation that exist in current allocation policy. The Committee will need to develop rating scales and weights for these attributes as well and is interested in community feedback on these attributes.

Table 3: OPTN Liver & Intestinal Transplantation Committee Identified Attributes for Intestine Allocation

	Medical Urgency	Post-Transplant Survival	Candidate Biology	Patient Access	Placement Efficiency
Attributes	• Status 1 vs. Status 2		• Candidate blood type	• Waiting time • Prior living donor	• Travel Efficiency • Proximity Efficiency

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[120] Ibid.

The National Liver Review Board and Exceptions

The previous concept paper included a detailed description of the Committee's initial plan to incorporate MELD or PELD exceptions and the NLRB into the continuous distribution framework. Since the last concept paper was released, the Committee has not further discussed the NLRB and MELD/PELD exceptions. However, the Committee will need to determine how to incorporate these aspects of allocation into the points-based framework.

Next Steps

As described previously, the Committee is making progress in the project and much work remains to be done. Once the Committee builds the rating scales and determines initial weights for each attribute, they will work to submit a modeling request to the SRTR. Modeling requests will help inform the potential impact of the policy changes on the allocations system. The Committee plans to submit at least two modeling requests. The first request will be used to get a general understanding of how the proposed changes will impact the system. Based on the results of the first request, the Committee will then submit a second request that will include more specific weights as the Committee moves towards a final policy proposal.

Most importantly, members of the Community are asked to participate in the values prioritization exercise currently available on the OPTN website. The results of this exercise will be important information for the Committee when determining the weights of different attributes and goals.

Compliance Analysis

The NOTA and OPTN Final Rule

The Committees submit this concept paper under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[121] The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[122] While this paper does not propose policy changes at this time, the concepts presented in this paper:

Are based on sound medical judgment:[123] The construction of the individual ratings scales and weights will be based on objective data, including simulation modeling and published research. The

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[121] 42 CFR §121.4(a).
[122] 42 C.F.R. §121.8(a)
[123] 42 CFR §121.8(a)(1).

Committee will rely upon peer-reviewed literature and data analyses as well their own clinical experience and judgment in making determinations regarding assigning weights and ratings to each attribute.

Seek to achieve the best use of donated organs:[124] The Committee will need to balance how to prioritize the most medically urgent candidates against the need to optimize post-transplant outcomes, ultimately resulting in the best use of donated organs. Before the policy proposal is released for public comment, it will be modeled by the SRTR to assess its impact on waitlist mortality and post-transplant outcomes. If necessary, the Committee will adjust the weighting of the attributes to balance these outcomes.

Are specific for each organ:[125] In this case, the allocation systems will be tailored to livers and intestines.

Are designed to avoid wasting organs:[126] The Committee identified multiple attributes specifically designed to avoid wasting organs. If necessary, the Committee will be able to adjust the weighting of the attributes to balance the number of transplants against other attributes.

Are designed to…promote patient access to transplantation:[127] The Committee identified several attributes that specifically ensure similarly situated candidates have equitable opportunities to receive an organ offer. The inclusion of these attributes is likely to increase access to transplantation for these candidates.

Are designed to…promote the efficient management of organ placement:[128] The Committee will consider indicators of efficiency associated with procuring and transplanting livers and intestines, including travel costs and the proximity between the donor and transplant hospitals.

Not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]:[129] The Committee is considering the candidate's place of listing to the extent that is required for the purpose of achieving efficient placement of the organs, specifically for travel efficiency, placement efficiency, and supply/demand.

Consider whether to adopt transition procedures:[130] A points-based framework will facilitate the use of transition procedures for existing candidates. For example, the OPTN may be able to compare the policy proposal with the results of a revealed preference analysis and modeling to determine who is impacted and if there is a need for transition procedures. This would allow members and patients time to prepare for these changes.

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[124] 42 CFR §121.8(a)(2).
[125] 42 CFR §121.8(a)(4).
[126] 42 CFR §121.8(a)(5).
[127] 42 CFR §121.8(a)(2).
[128] 42 CFR §121.8(a)(5).
[129] 42 CFR §121.8(a)(8).
[130] 42 C.F.R. § 121.8(d). The Final Rule requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.

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Conclusion

This request is just one step in a multi-phase project to convert the current classification-based allocation system to a continuous distribution framework. Continuous distribution utilizes a points-based system for organ allocation and will be more equitable, transparent, and flexible than the current allocation system. By separating the specific attributes and developing attribute specific rating scales and weights, there will be more nuanced solutions for how certain candidate populations are prioritized, thereby improving equity in access to organ transplantation.

This project serves as an opportunity to rethink how the OPTN and the transplant community develops organ allocation policies. This request for feedback explains the work the Committee has completed to date and seeks community feedback on the project thus far. The Committee is also interested the Community's input on the overall project plan and any other aspects of the allocation system that are relevant to continuous distribution.

Consideration for the Community

The Committee is seeking public comment feedback on the following items related to the continuous distribution of livers and intestines:

- Do you agree with the attributes the Committee plans to include in the first iteration of continuous distribution? If not, are there attributes that are included that you think should not be included? Or, are there attributes that aren't included but you think they should be included?
- Do you think the Committee should switch from utilizing MELD and PELD to OPOM as the medical urgency scores in liver allocation to OPOM at the same time as continuous distribution?
- Do you agree with the Committee's decision to not include a factor for post-transplant survival? If not, why not?
- Please provide any feedback on how the Committee should incorporate a factor for height or BSA.
- Please provide any feedback on how prior-living donors should be prioritized.
- Please provide any feedback on ways the Committee can increase the number of split liver transplants in the new allocation framework.
- Please provide any feedback on how the Committee should consider placement efficiency.
- Please provide feedback on how the Committee should incorporate population density.
- Do you think the Committee should consider a continuous donor quality scale or do you prefer to maintain the use of DCD/Age of 70 in the new framework?
- Are there any other donor factors the Committee should consider?
- Please provide any feedback on how the Committee should consider intestine allocation.
- Please provide any feedback on any other aspects of this request for feedback.

Appendix: Glossary of Terms

The following terms are used throughout the concept paper.

Acuity Circles (AC): The current liver allocation policy that utilizes a series of concentric circles and MELD/PELD groupings to rank liver and liver-intestine candidates on the match run.

Analytical Hierarchy Process (AHP): An AHP is an example of a stated preference analysis. This analysis asks participants to state their preferences in a pairwise comparison.

Attribute: Attributes are criteria used to classify, sort and prioritize candidates.

Classification-based framework: A classification-based framework groups similar candidates into classifications or groupings. The candidates are then sorted within those classifications. This is the framework currently used to allocate organs.

Composite Allocation Score: A composite allocation score combines points from multiple attributes together. This concept paper proposes the use of composite allocation scores in a points-based framework.

Concentric Circles: This distribution framework utilizes the distance between the donor hospital and the candidate's transplant hospital to prioritize organ offers to candidates. These distances are grouped into zones at specific nautical mile distances.

Calculated Panel Reactive Antibody (CPRA): The percentage of deceased donors expected to have one or more of the unacceptable antigens indicated on the waiting list for the candidate. The CPRA is derived from HLA antigen/allele group and haplotype frequencies for the different ethnic groups in proportion to their representation in the national deceased donor population.

Exception (standardized): When the calculated MELD or PELD score does not reflect the candidate's medical urgency, a liver transplant program may request an exception score. A candidate that meets the criteria for one of nine diagnoses in OPTN policy is approved for a standardized exception.

Exception (non-standard): When the calculated MELD or PELD score does not reflect the candidate's medical urgency, a liver transplant program may request an exception score. If the candidate does not meet the criteria for standardized exception as outlined in OPTN policy, the request is considered by the National Liver Review Board (NLRB).

Framework: A collection of policies and procedures used to distribute organs. Examples include concentric circles and continuous distribution.

Goals: Five goals constitute the overall composite allocation score. These goals align with the requirements in the NOTA and the OPTN Final Rule: Medical urgency, post-transplant survival, candidate biology, patient access, placement efficiency**.**

Human leukocyte antigen (HLA): A type of molecule found on the surface of most cells in the body. Human leukocyte antigens play an important part in the body's immune response to foreign

substances.

Ischemic Time: Ischemic time is broken into three subparts: procurement, transit, and transplant time. Procurement time begins at cross-clamp and ends at transit departure time. OPO and procurement practices, among other things, influence procurement related ischemic time. Transit time is the time in between departure from the procurement location and delivery at the transplant hospital. Transplant time is then the time between delivery at the transplant hospital and the start of anastomosis.

MELD: Model for End Stage Liver Disease; the scoring system used to measure illness severity in the allocation of livers to adults and adolescents.

MMaT: Medium MELD at transplant; The MMaT is calculated by using the median of the MELD scores for transplants performed within 150 nautical miles (NM) of each donor hospital. Exception candidates on a match run are assigned an exception score relative to the MMaT for the donor hospital where match is run and ranked against each other based on time since submission of earliest approved exception

NLRB: National Liver Review Board; A review board of members drawn from a nationwide pool of liver transplant physicians and surgeons, who review non-standard exception requests from transplant programs for candidates whose calculated MELD score or PELD score does not accurately reflect the candidate's medical urgency for transplant.

PELD: Pediatric End Stage Liver Disease; The scoring system used to measure illness severity in the allocation of livers to candidates under the age of 12.

Points-based framework: A points-based framework gives each candidate a score or points. Organs are then offered in descending order based upon the candidate's score. This concept paper proposes a points-based framework for organ allocation.

Rating Scale: A rating scale describes how much preference is provided to candidates within each attribute. Applying the rating scale to each candidate's information and combining it with the weight of the attribute results in an overall composite score for prioritizing candidates.

Revealed Preference: A revealed preference analysis looks at actual decisions to determine the implicit preferences of the decision maker. This is compared with a stated preference analysis (for example, AHP) that asks the decision maker to state their preferences in an experiment.

Weight: Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.

Continuous Distribution Resources

For additional information on the continuous distribution framework and the work of the OPTN, visit: https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/

The OPTN Liver and Intestinal Organ Transplantation Committee previously released a concept paper on the continuous distribution of livers and intestines.
- *Continuous Distribution of Livers and Intestines Concept Paper*

Other continuous distribution resources:
- *Continuous Distribution of Livers and Intestines*
- *Ethical Considerations of Continuous Distribution in Organ Allocation White Paper*
- *Continuous Distribution of Lungs*
- *Continuous Distribution of Kidneys and Pancreata*