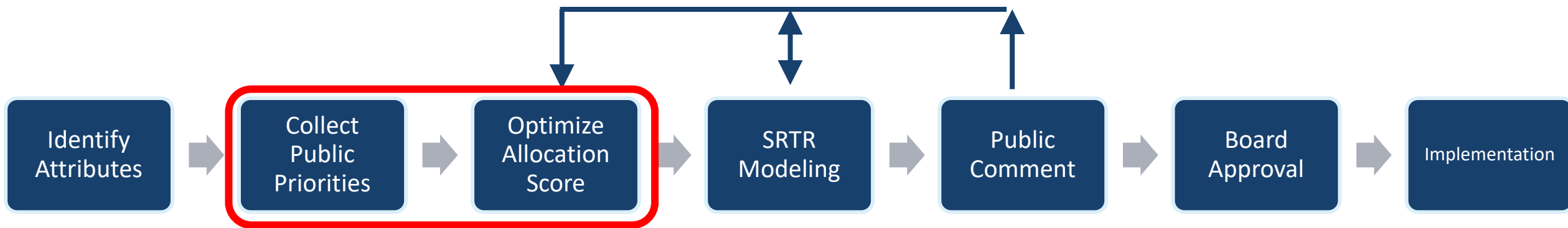


Continuous Distribution of Livers and Intestines Update, Summer 2024

*OPTN Liver & Intestinal Organ Transplantation Committee
Scott Biggins, Chair*

Purpose of Request for Feedback

- Update community on the progress to date
- Seek community feedback to help inform the new allocation framework



Request for Feedback

- Provides an update on the liver and intestine continuous distribution project
 - Provides further detail on the **proposed attributes for the first iteration of continuous distribution**
 - Overview of next steps in the project
- Asks for community feedback on:
 - Proposed attributes
 - Project plan and approach

Rationale

- Provide a **more equitable approach** to matching liver and intestine candidates and donors
- **Remove hard boundaries** that prevent liver and intestine candidates from being prioritized further on the match run
- **Consider multiple candidate attributes all at once** through a composite allocation score instead of within categories by sequence
- Establish a **system that is flexible** enough to work for each organ type

Project Plan

Determine attributes

- What factors should be included in the framework?
- What exists in current policy?
- Are there factors not currently in policy that could be incorporated?

Define Attributes

- What is the purpose of each attribute?
- What outcome measure can be used to determine success for each attribute?
- How should points be assigned to candidates for each attribute?

Mathematical optimization

- Continue to iterate on the development of rating scales
- Deliberate over tradeoffs between attributes that may conflict with one another
- Determine weights of attributes
- Use mathematical optimization to find policy scenarios that meet the Committee's preferred outcome metrics for the new allocation system

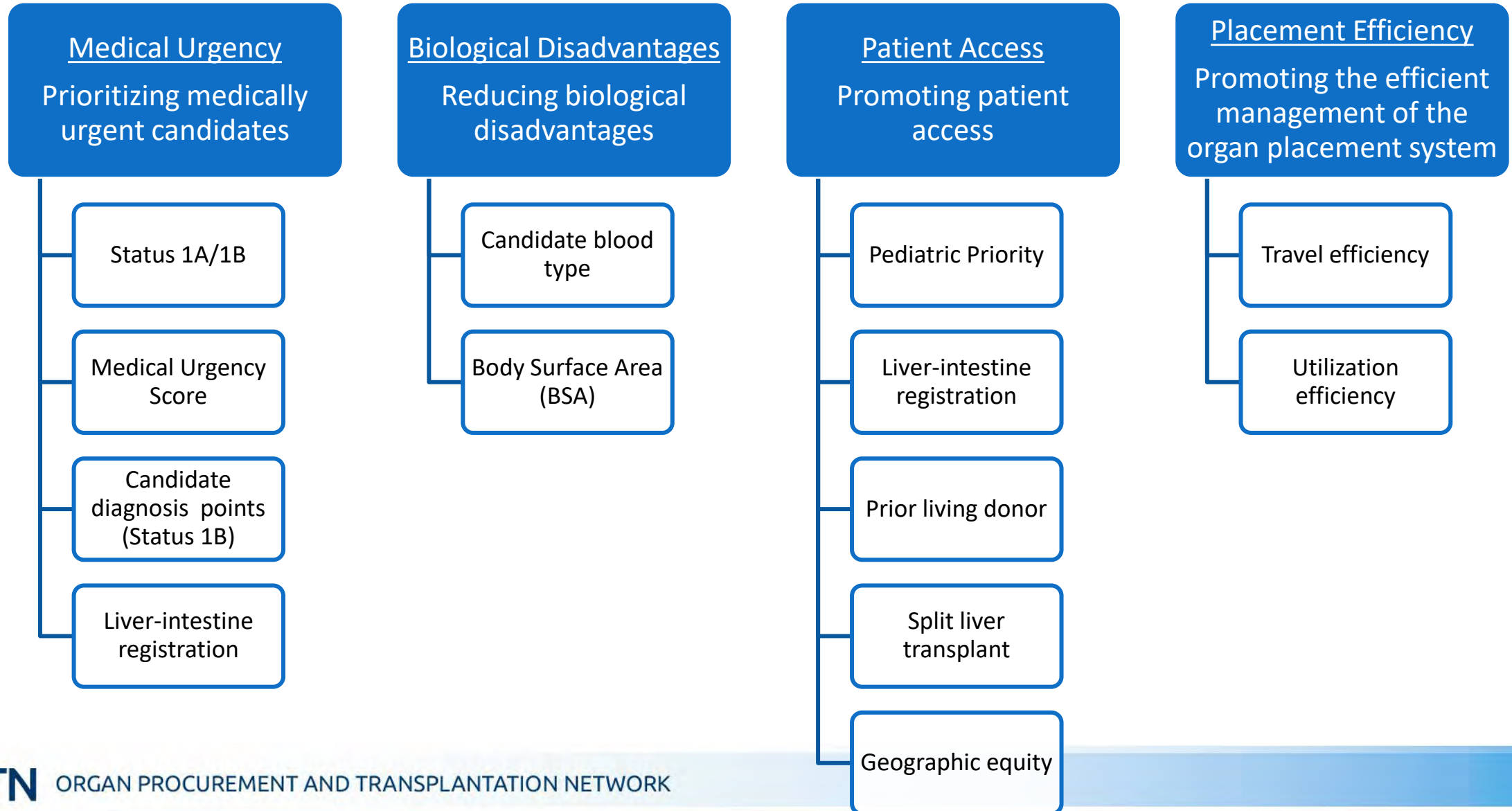
OASim Modeling

- Use Organ Allocation Simulator modeling to confirm expected outcomes of final policy scenarios

Final Proposal

- Determine final policy scenario for public comment and OPTN Board of Directors' consideration

Identified Attributes for Liver CD



Identified Attributes for Liver CD

- The Committee has gone through the process of determining the purpose and metrics of success for each attribute and developed initial rating scales for the majority of attributes
- This update paper focuses on the following:
 - Body Surface Area (BSA)
 - Medical Urgency Score
 - Utilization Efficiency
 - Pediatric Priority
 - Travel Efficiency
 - Exceptions, including HCC stratification
 - Mathematical Optimization

Body Surface Area Attribute

Purpose	Metric of Success
• Provide equal access to transplant for candidates regardless of their stature	• Sequence number: number of match runs with candidate below certain BSA in top 10 divided by total active time on the waitlist with MELD/PELD above 15

- Height, AP diameter, and BSA were reviewed as inputs to a size-based attribute
- BSA was determined to be the appropriate input
 - More closely correlates to AP diameter than height*
 - Provides a three-dimensional measurement

*Little CJ et al Transplant Direct 2024 (PMID 38769984)

Body Surface Area Attribute

- Two options will be reviewed in the mathematical optimization dashboard
- The Committee remains interested in exploring more continuous rating scales and donor modifiers

Rating scale: Binary (Y/N)

Option 1: Candidates receive points if their BSA is in the bottom 15th percentile

Option 2: Same as option 1, plus additional points are awarded to candidates in the bottom 5th percentile of BSA

Donor modifier: If a donor is 18 years of age or the donor is in the bottom 10th percentile of BSA

Medical Urgency Score Attribute

	MELD	<u>dynaMELD</u>	OPOM
Exceptions	Does not incorporate	Does not incorporate	Two trees – one for candidates with an active HCC exception; one for candidates with non exception or a non-HCC exception
Pediatric	PELD	Does not include pediatric candidates	POPOM – current version incorporates age and time on the waiting list
Model	Proportional hazards framework	Proportional hazards framework incorporated with neural networks	Tree-based structure
Variables	Sex, serum sodium, creatinine, INR, bilirubin, albumin	- Sex, serum sodium, creatinine, INR, bilirubin, albumin - Whether primary diagnosis is PSC or PBC - Additional rate of change variables: serum albumin, serum bilirubin, serum creatinine, serum sodium, INR	- Sex, serum sodium, creatinine, INR, bilirubin, albumin - Lab MELD 3.0 score, dialysis in prior week, time since listing - Additional HCC variables: number of tumors, sum of tumor sizes, AFP
Model Evaluation	All models exhibited similar AUC/C-statistics, suggesting that each model has a similar ability to distinguish between candidates who will survive without a transplant versus those who will not, and correctly rank pairs of these candidates accordingly. However, because each study employed different study designs, data cohorts, and analytical methods, the AUC/C-statistics presented for each model are not directly comparable. Direct comparisons of model performance necessitate further information and validation.		

Medical Urgency Score Attribute

- The Committee has agreed to utilize MELD/PELD as the medical urgency scores within the first version of continuous distribution
 - **Robust** and continues to hold up
 - Recent changes to MELD 3.0 have been **positive and helped address equity**
 - **Changing from MELD/PELD may be too much change** and do not understand the unintended consequences
 - Shown its strengths and current system is great but **acknowledges that exceptions could be modeled better**
 - Explore possibility to use MELD but **collect prospective data on other models for evaluation for CD 2.0**
- Continue to work with OPOM and dynaMELD teams to explore how each respective model could utilize their innovative frameworks to address standard exceptions related to medical urgency

Utilization Efficiency Attribute

- Previously referred to as the *proximity efficiency* attribute
- Purpose: Increase efficiency in organ placement system (**make difficult to place grafts less difficult to place**)
- Next steps: determine how to award points to candidates to increase use of **medically complex livers**

Candidate

- To be determined

Donor

- Medically complex livers
 - DCD
 - Age over 70

Other Topics

Pediatric Priority Attribute

- Seeking feedback on all pediatric population considerations

Travel Efficiency Attribute

- Seeking feedback on when organizations drive vs fly for organ procurement

Exceptions

- Seeking feedback on how to incorporate HCC stratification as well as other standard exceptions into continuous distribution

Mathematical Optimization Dashboard

- Upcoming phase of the project
- Will be used to help in:
 - Finalize rating scales for each attribute
 - Discussing tradeoffs between attributes
 - Determine weight for each attribute compared to other attributes



Next Steps

- Review community feedback
- The Committee will:
 - **Finish developing initial rating scales** for all attributes
 - Determine how to **incorporate exceptions** into the framework
 - Use **mathematical optimization** dashboard
 - Build draft framework and **submit modeling request**
- Continuously update and engage community throughout the entirety of the project development

Next Steps

- Requesting feedback on the following topics:
 - **All identified attributes** including their drafted purposes and initial rating scales.
 - The Committee's decision to utilize **MELD and PELD as the medical urgency score** model
 - Specific considerations for the **pediatric population**
 - When your organization begins to fly rather than drive for organ procurement as well as any feedback on **travel practices**
 - The **BSA attribute** including the decision to use BSA, the options for rating scales, and donor modifiers
 - The **utilization efficiency attribute** including input of the options for how to award candidates points and the definition of a medically urgency liver offer
- What areas can be improved to address the needs of patients including areas that need better communication and education?
- Please provide any feedback on any other aspects of this project including any additional considerations that are not addressed in this paper which warrant Committee discussion.

FAQs

- Is the list of attributes finalized?
- How will weights be assigned?
- Have the rating scales been determined for each attribute?
- Will this look similar to lung's continuous distribution proposal?
- How will liver continuous distribution address efficiency concerns?

Additional Questions?

- Please direct all questions on the OPTN Liver and Intestinal Organ Transplantation Committee's request for feedback *Update on Continuous Distribution of Livers and Intestines* to Meghan McDermott at Meghan.McDermott@unos.org

Provide Feedback

Submit public comments on the OPTN website:

- [Add current cycle dates]
- **optn.transplant.hrsa.gov**

