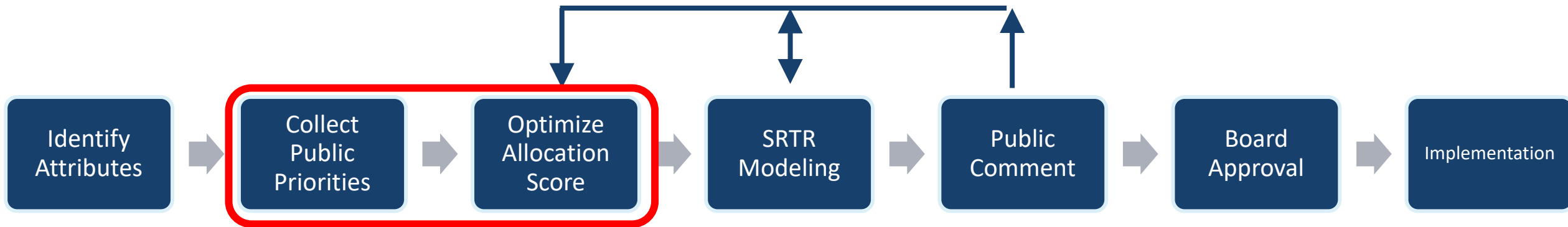


# Continuous Distribution of Livers and Intestines Update, Summer 2024

*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

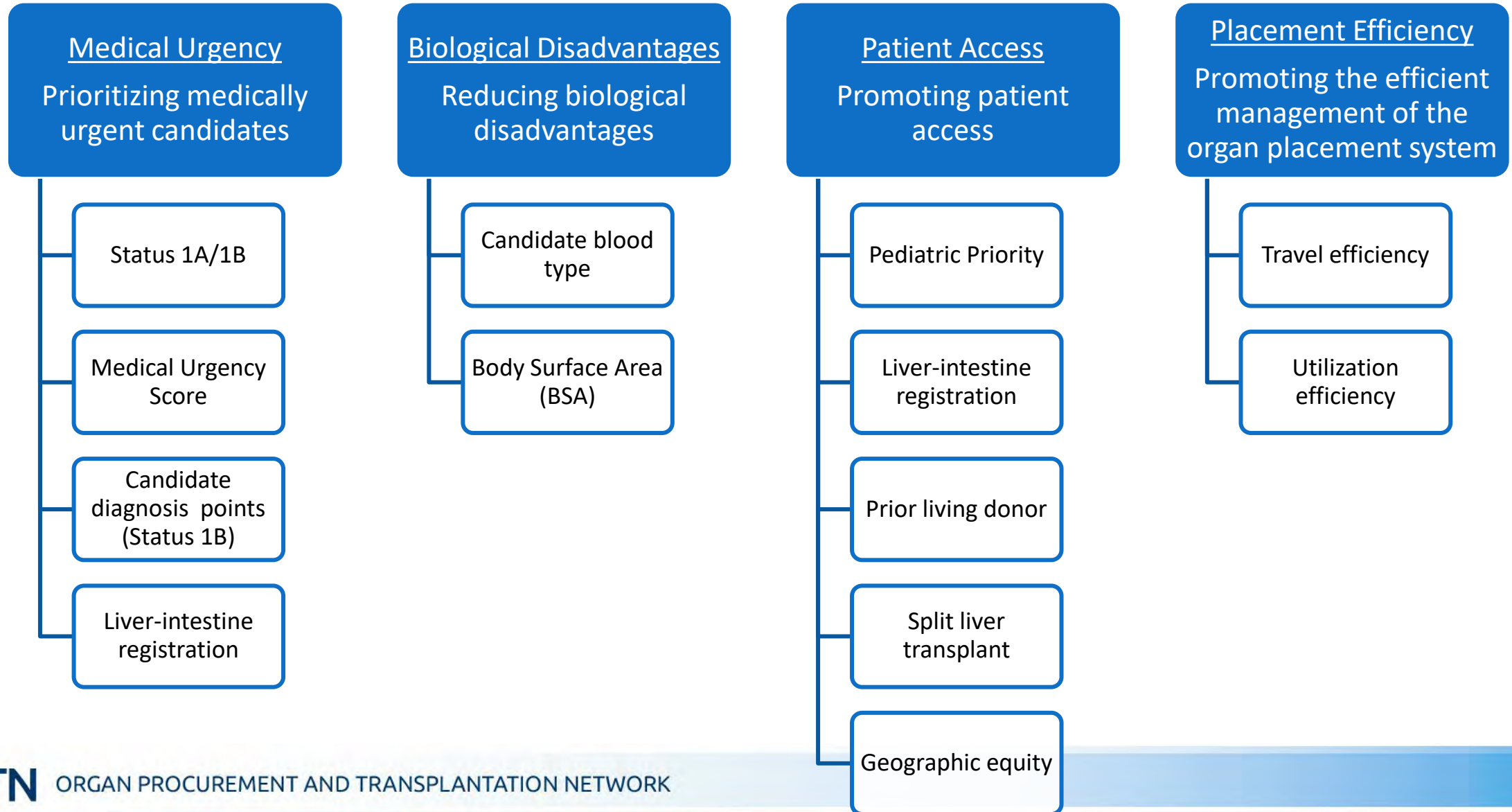
## OASim Modeling

- 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
<ul style="list-style-type: none"><li>• Provide equal access to transplant for candidates regardless of their stature</li></ul>	<ul style="list-style-type: none"><li>• 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</li></ul>

- 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 15<sup>th</sup> percentile

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

**Donor modifier:** If a donor is 18 years of age or the donor is in the bottom 10<sup>th</sup> percentile of BSA

# Medical Urgency Score Attribute

	MELD	<u>dynaMELD</u>	OPOM
Exceptions	<ul style="list-style-type: none"> <li>Does not incorporate</li> </ul>	<ul style="list-style-type: none"> <li>Does not incorporate</li> </ul>	<ul style="list-style-type: none"> <li>Two trees – one for candidates with an active HCC exception; one for candidates with non exception or a non-HCC exception</li> </ul>
Pediatric	<ul style="list-style-type: none"> <li>PELD</li> </ul>	<ul style="list-style-type: none"> <li>Does not include pediatric candidates</li> </ul>	<ul style="list-style-type: none"> <li>POPOM – current version incorporates age and time on the waiting list</li> </ul>
Model	<ul style="list-style-type: none"> <li>Proportional hazards framework</li> </ul>	<ul style="list-style-type: none"> <li>Proportional hazards framework incorporated with neural networks</li> </ul>	<ul style="list-style-type: none"> <li>Tree-based structure</li> </ul>
Variables	<ul style="list-style-type: none"> <li>Sex, serum sodium, creatinine, INR, bilirubin, albumin</li> </ul>	<ul style="list-style-type: none"> <li>Sex, serum sodium, creatinine, INR, bilirubin, albumin</li> <li>Whether primary diagnosis is PSC or PBC</li> <li>Additional rate of change variables: serum albumin, serum bilirubin, serum creatinine, serum sodium, INR</li> </ul>	<ul style="list-style-type: none"> <li>Sex, serum sodium, creatinine, INR, bilirubin, albumin</li> <li>Lab MELD 3.0 score, dialysis in prior week, time since listing</li> <li>Additional HCC variables: number of tumors, sum of tumor sizes, AFP</li> </ul>
Model Evaluation	<ul style="list-style-type: none"> <li>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.</li> </ul>		

# 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](mailto:Meghan.McDermott@unos.org)

# Provide Feedback

Submit public comments on the OPTN website:

- [Add current cycle dates]
- **[optn.transplant.hrsa.gov](https://optn.transplant.hrsa.gov)**

