

Update on Continuous Distribution of Livers and Intestines

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

Continuous Distribution

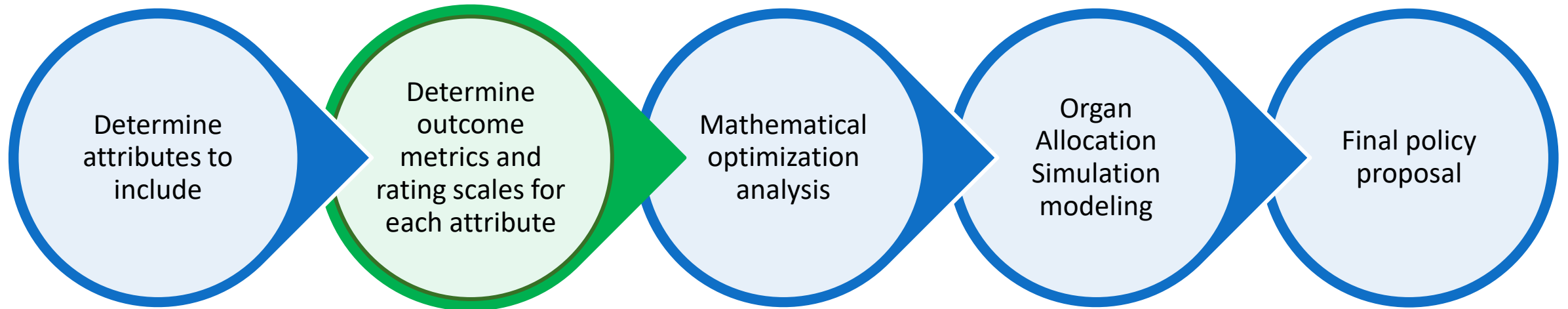
- A more **fair and flexible** way to allocate deceased donor organs
- A **patient-centric** framework that considers all candidates at the same time, with no need for classifications
- A system that ranks candidates by their **composite allocation scores**
- A **major change** in the allocation system

For more information about continuous distribution visit:

<https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>

Purpose of Concept Paper

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



Committee Update

- Provides information on:
 - Results of the values prioritization exercise (VPE)
 - Progress towards mathematical optimization analysis
 - Ongoing discussions about attributes

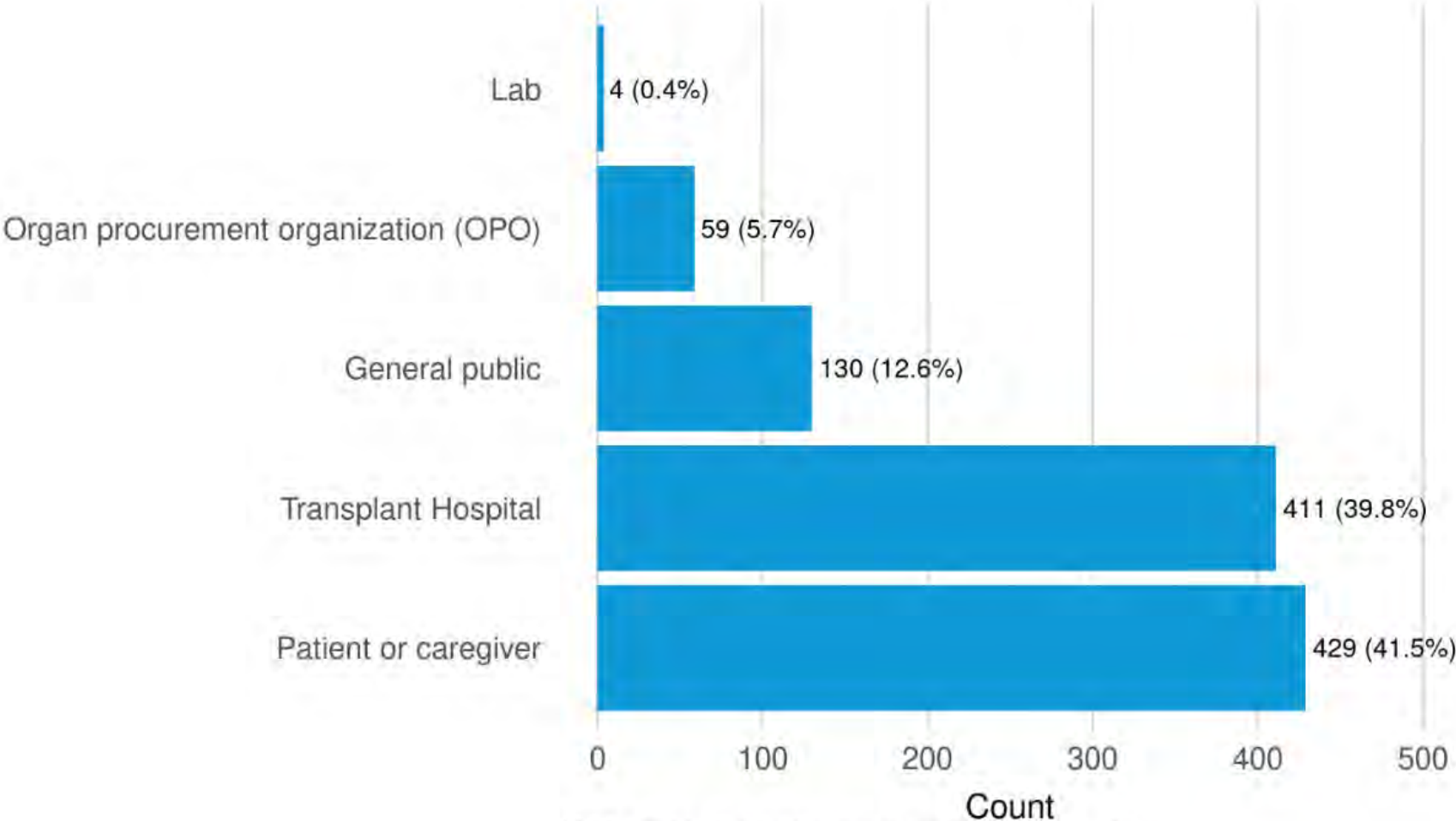
Values Prioritization Exercise Results

Values Prioritization Exercise

- Open for public participation during the winter 2023 public comment period
- 1,033 participants, with patients and caregivers as the largest participating stakeholder
- Results will inform:
 - Decisions on which attributes or goals to prioritize in the mathematical optimization analysis
 - Discussions regarding tradeoffs between different attributes

Values Prioritization Exercise Results

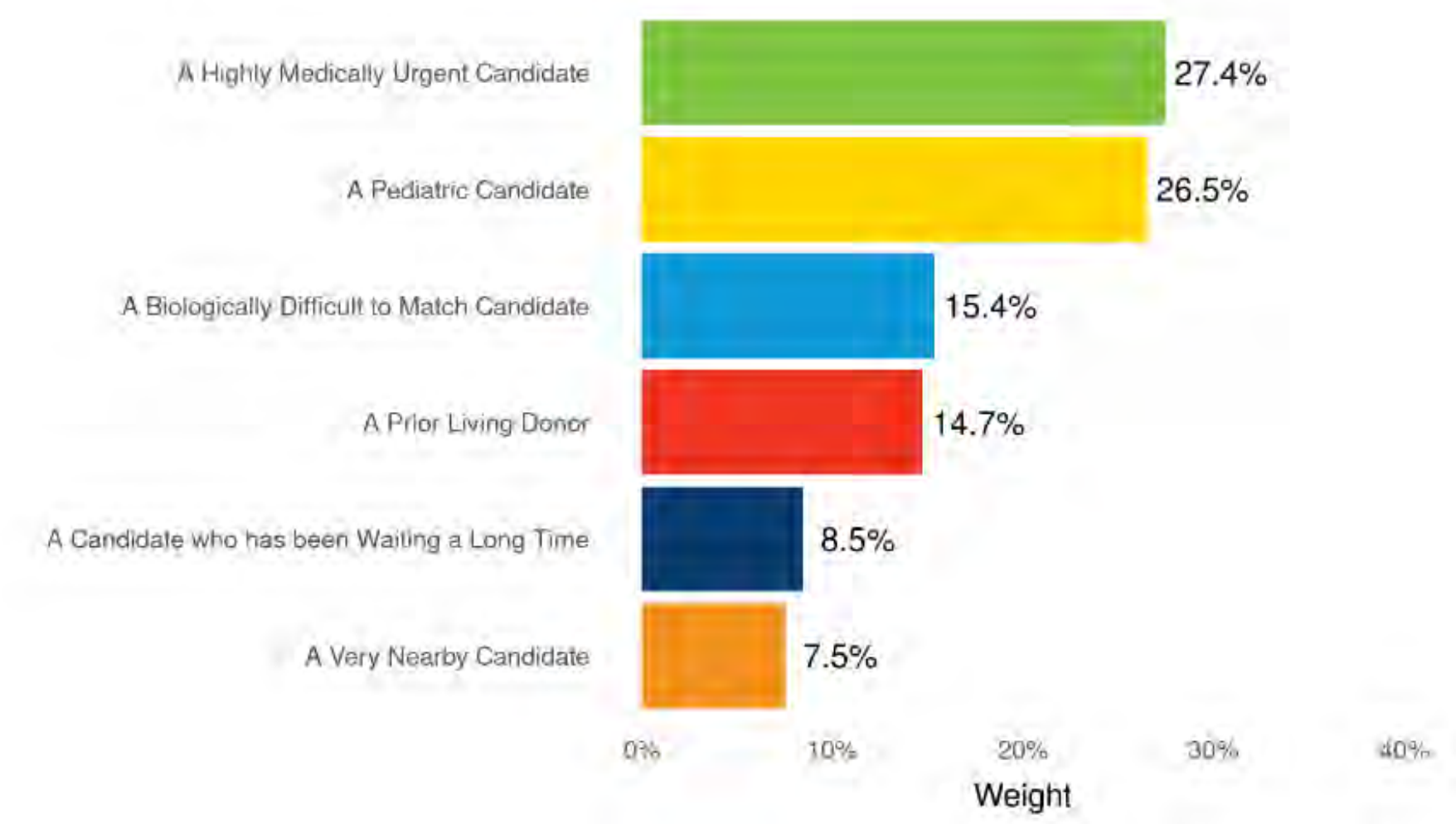
Participation by Transplant Affiliation



1033 total individuals participated in the exercise

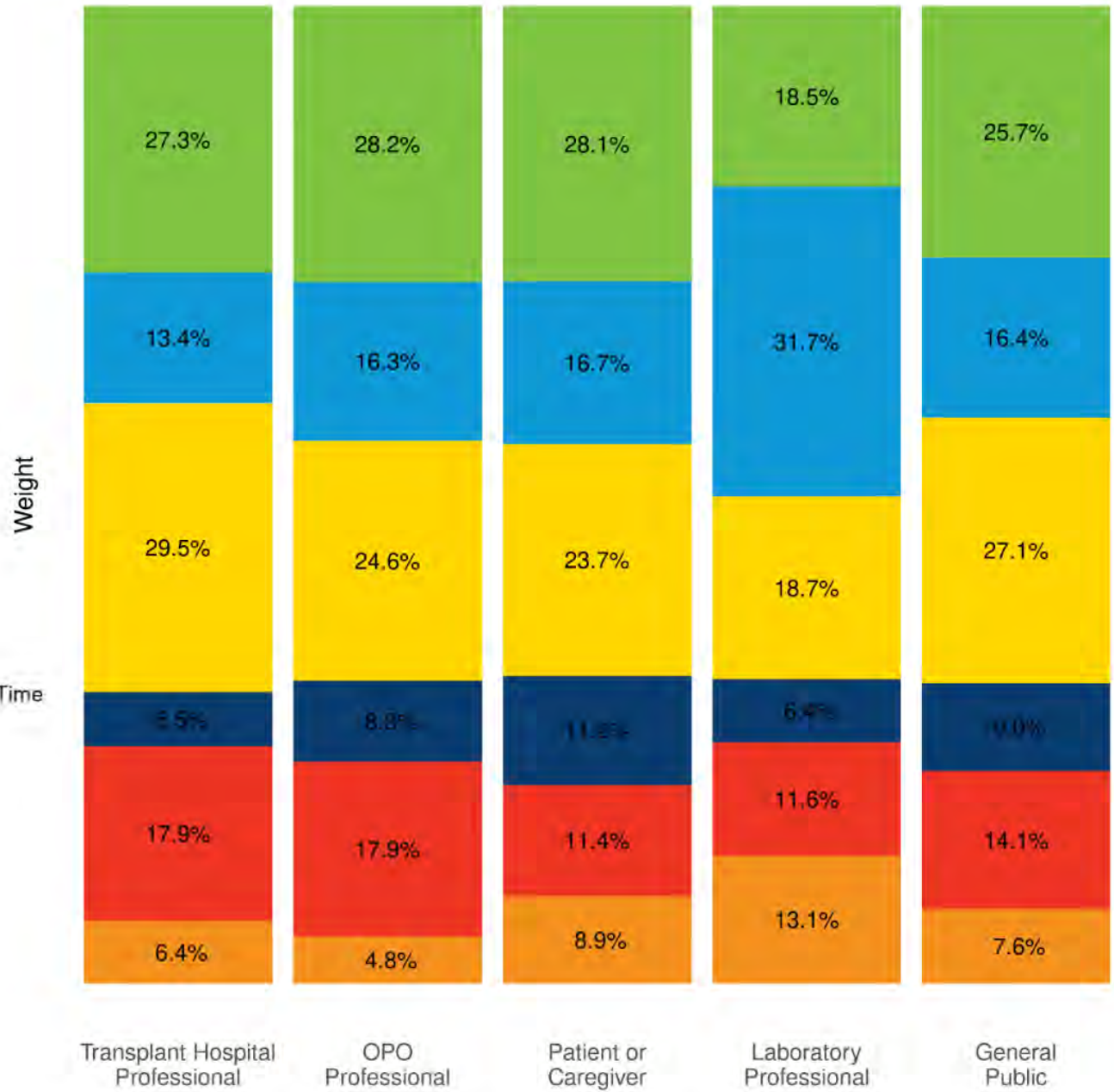
Values Prioritization Exercise Results

Overall Ratings, Population-Adjusted



Values Prioritization Exercise Results

Ratings by Transplant Affiliation

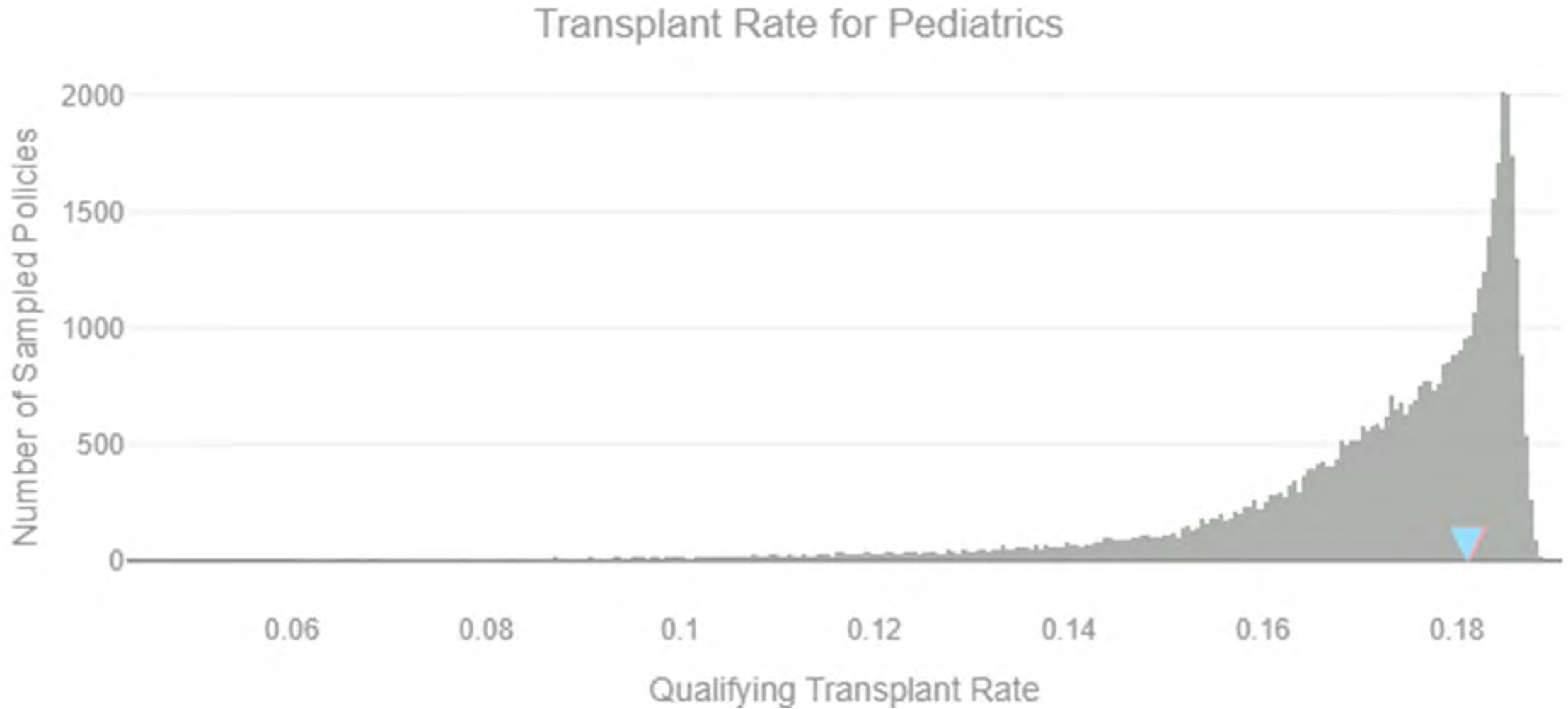


Mathematical Optimization Analysis

Mathematical Optimization Analysis

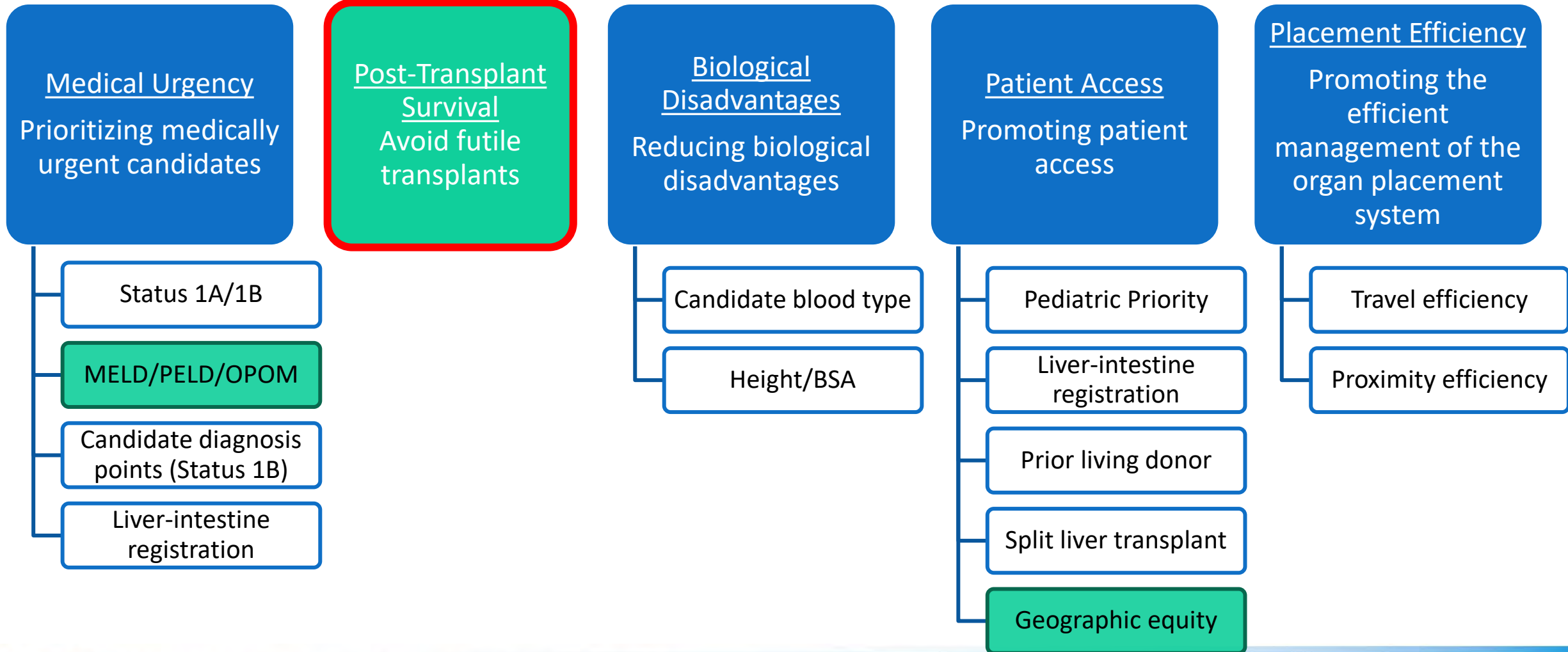
- Uses machine learning and artificial intelligence to look at thousands of potential policy scenarios
- First step is to determine the specific outcomes each attribute intends to achieve
 - Then find the policy scenario(s) that will achieve those outcomes
- Allows for the ability to better quantify, understand, and deliberate over tradeoffs between attributes that may conflict with one another

MIT example



Ongoing Attribute Discussions

Ongoing Attribute Discussions



Post-Transplant Survival

- Previous update explained the Committee's decision to not include post-transplant survival as an attribute
- Since that time:
 - Public comment feedback was submitted in support of including an attribute for post-transplant survival
 - A new liver-estimated post-transplant survival (L-EPTS) model was developed

Post-Transplant Survival

How the system accounts for
post-transplant survival

MELD score
capped at 40

Monitoring on
one-year
survival after
liver transplant

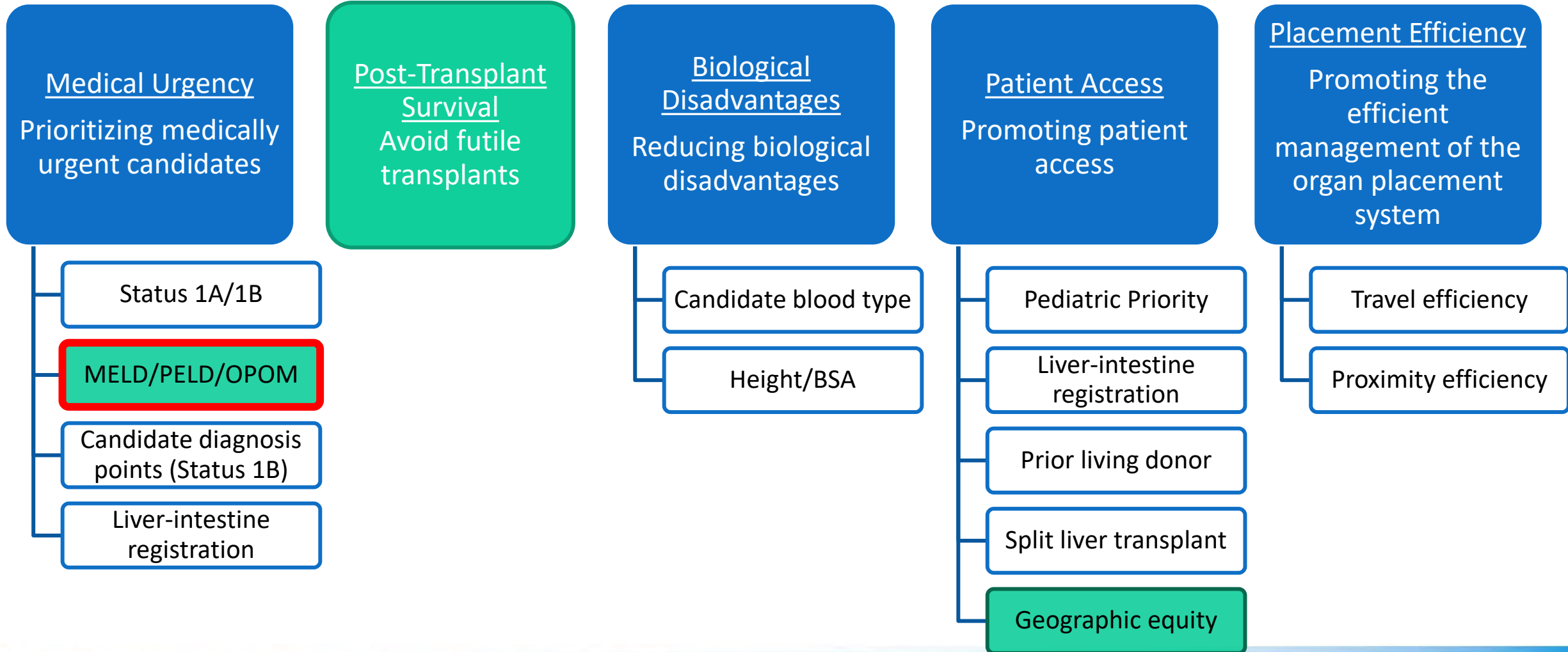
Transplant
program listing
practices

Specific criteria
for exceptions

Post-Transplant Survival

- The Committee continues to agree that the allocation system already accounts for post-transplant survival appropriately and therefore does not intend to include a specific attribute for post-transplant survival in the first iteration of continuous distribution

Ongoing Attribute Discussions



Medical Urgency Score

MELD/PELD

Calculation utilizing objective laboratory values

Recently implemented MELD 3.0 and PELD Cr intends to better predict overall mortality risk

Does not interdigitate candidates with HCC

OPOM/POPOM

Machine learning techniques utilizing objective laboratory values

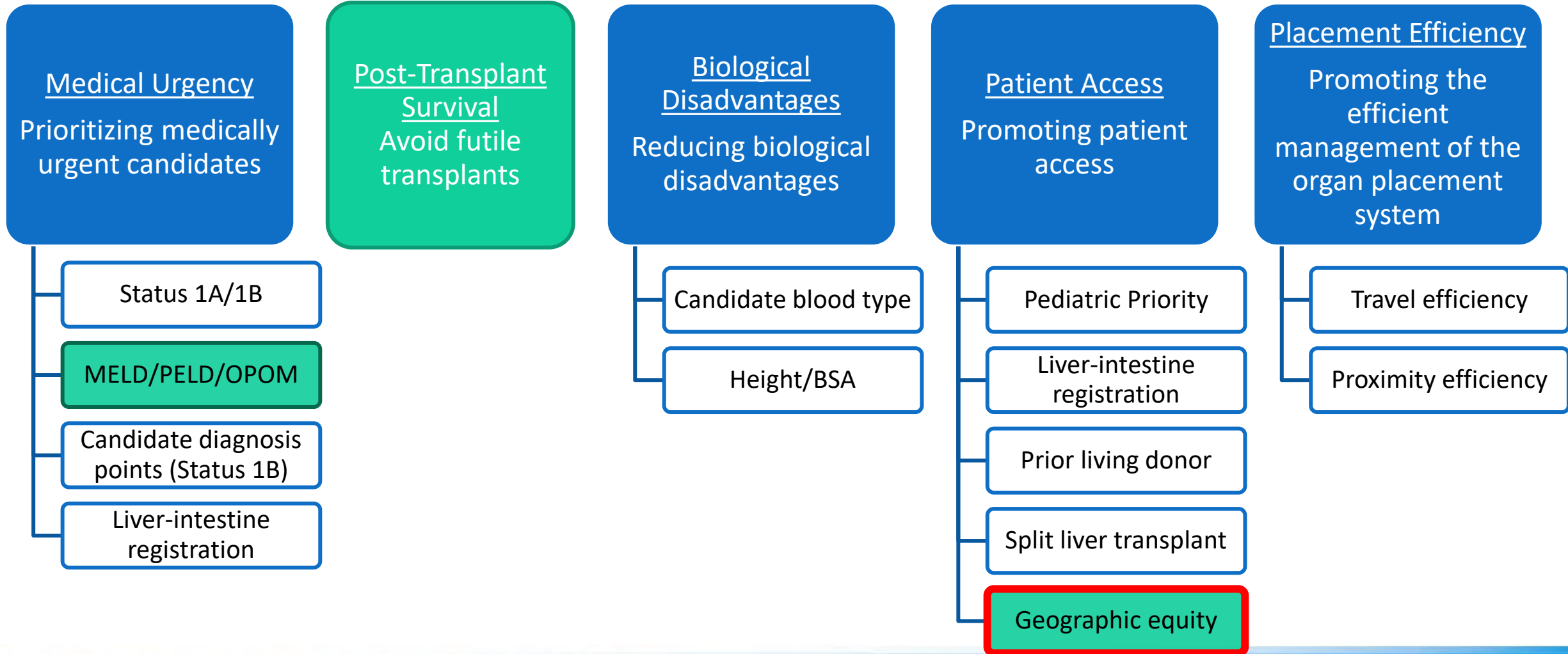
Has the potential to better rank candidates based on risk of waitlist mortality than MELD 3.0 and PELD Cr

Interdigitates candidates with HCC

Medical Urgency Score

- The Committee has continued to engage with the developers of OPOM
 - There remains interest in OPOM's potential to better predict waitlist mortality
- MELD/PELD and OPOM are planned to both be included in the mathematical optimization analysis
 - Results will inform a final decision for a medical urgency score

Ongoing Attribute Discussions

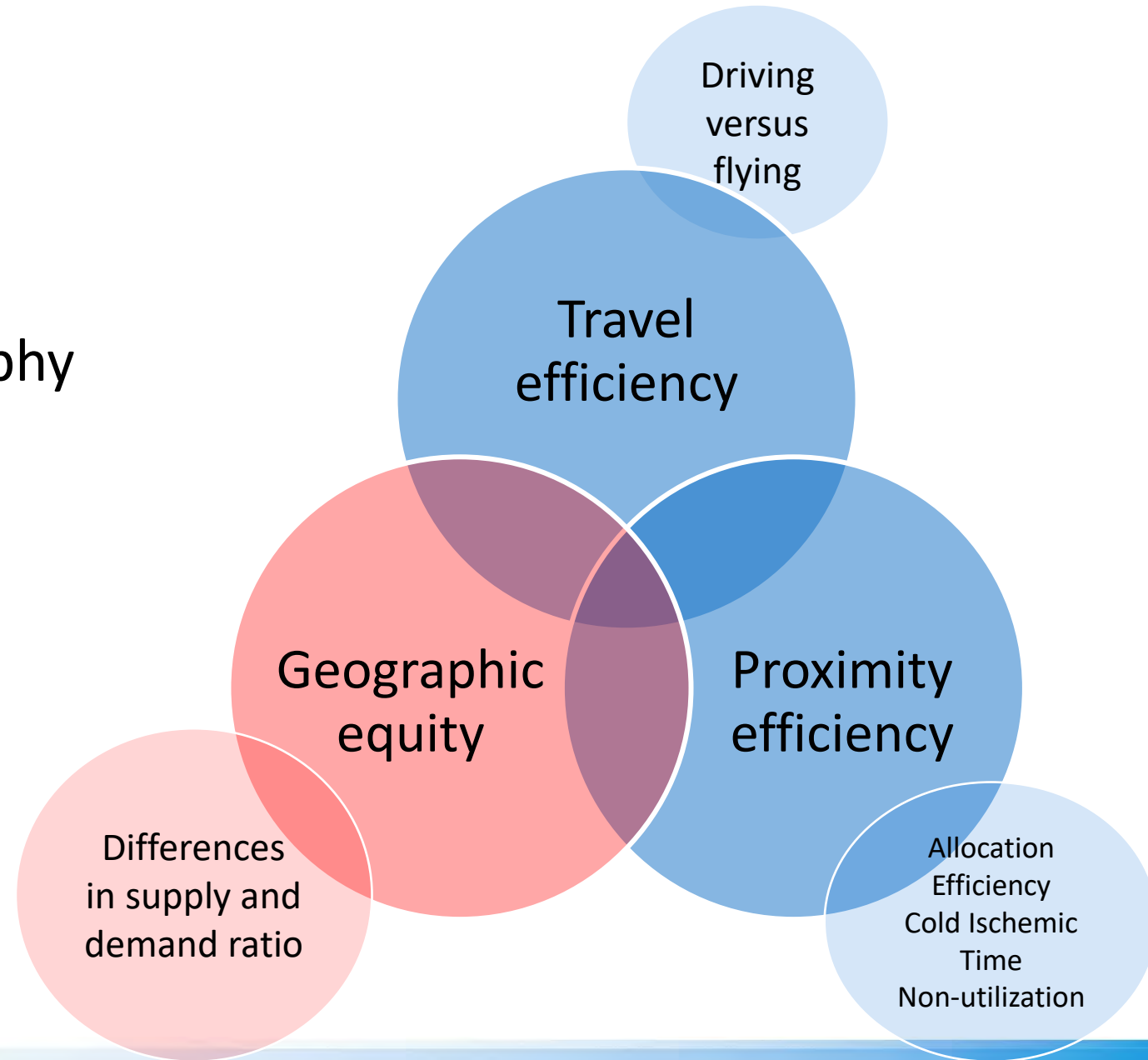


Geographic Equity

- Termed as “population density” in previous updates
- Updated terminology reflects the decision to broaden scope of attribute to reduce inherent differences in the ratio of donor supply and demand across the country

Geographic Equity

- There are multiple identified attributes that relate to geography
- These attributes impact each other

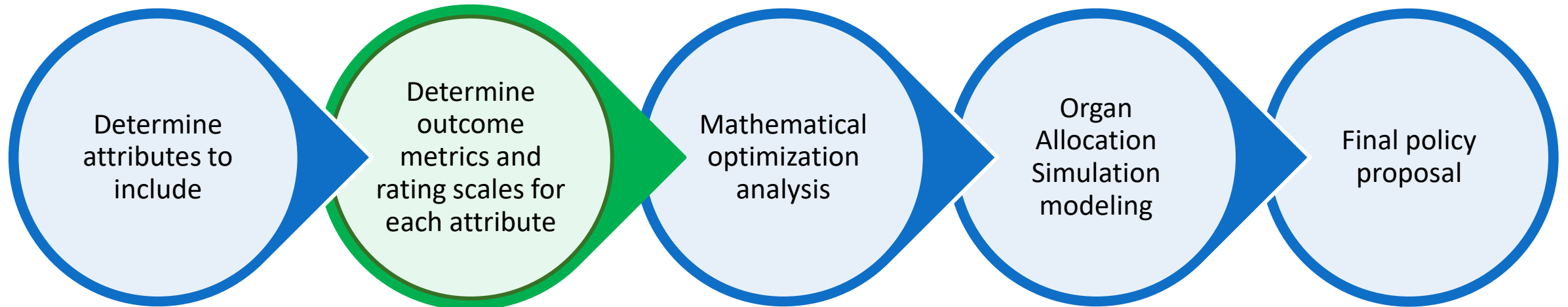


Geographic Equity

- Continued discussions will occur to identify the most appropriate way to incorporate geographic equity into a composite allocation score
- The Committee is considering developing a rating scale based on population density to address geographic equity
 - Results of the mathematical optimization analysis will inform an understanding of the potential impact

Next Steps

- Continue to work towards a mathematical optimization analysis and engage with the community for feedback and progress to date



Thank You For Listening!