

# OPTN Thoracic Organ Transplantation Committee Update

*Winter 2020 Regional Meetings  
Breakout Session*

# Agenda

- Thoracic Organ Transplantation Committee Update: **Heart-focused Projects** (~15 min)
- Proposal: National Heart Review Board for Pediatric Candidates (~15 min)
- Thoracic Organ Transplantation Committee Update: **Lung-focused Projects** (~15 min)

Speaker for first three discussion items:

- Continuous Distribution of Lungs Overview (~30 min)

Speaker:

# OPTN Thoracic Organ Transplantation Committee Update: Heart-focused Projects

# Committee Project Updates – Heart

- Problem Analysis
  - Reviewing Use of Exceptions for Status 2 Candidates on Intra-Aortic Balloon Pumps (IABP) – Guidance Document
- Post-implementation Review
  - Eliminate the Use of DSAs in Thoracic Distribution
  - Modifications to the Adult Heart Allocation System
- Public Comment
  - National Heart Review Board for Pediatrics

# Guidance Document for Use of Exceptions for Status 2 Candidates on Intra-Aortic Balloon Pumps (IABP)

- Opportunity to clarify what info is helpful regarding exception requests (initial and extensions)
- Initial focus on use of exceptions involving Status 2 candidates on IABP
- Subcommittee is considering:
  - Appropriate circumstances for using exceptions for Status 2 candidates on balloon pumps?
  - What information would have been helpful if included with submitted exception requests?
- Public comment period: August – October 2020
- Please provide feedback on what guidance is needed

# IT Implementation of Eliminate the Use of DSAs in Thoracic Distribution

- Replaces DSA in heart allocation policy with nautical mile distances between the transplant and donor hospitals
- Board approved June 2019
- Implemented January 9, 2020
- Any questions or early feedback on the policy change?

# National Heart Review Board for Pediatrics

*OPTN Thoracic Organ Transplantation Committee*

# Purpose of Proposal

- Address increase in pediatric heart Status 1A exceptions since criteria were updated
- Address variation in regional review board (RRB) members' pediatric expertise

# Proposal

- Create national review board for pediatric exceptions only
  - To review all pediatric heart 1A and 1B exception requests
- Proposed components
  - Address representation of pediatric programs
  - Establish voting process
  - Establish appeals process

# Representation

- Reviewers comprised of representatives from pediatric heart programs
- Each case randomly assigned to a group of 9 reviewers

# Voting

- Retrospective
- Reviewers have 3 days to vote or case is reassigned
- If no resolution within 6 days, the decision is based on votes cast to date
- Will use a new system in UNet<sup>SM</sup> (similar to National Liver Review Board)

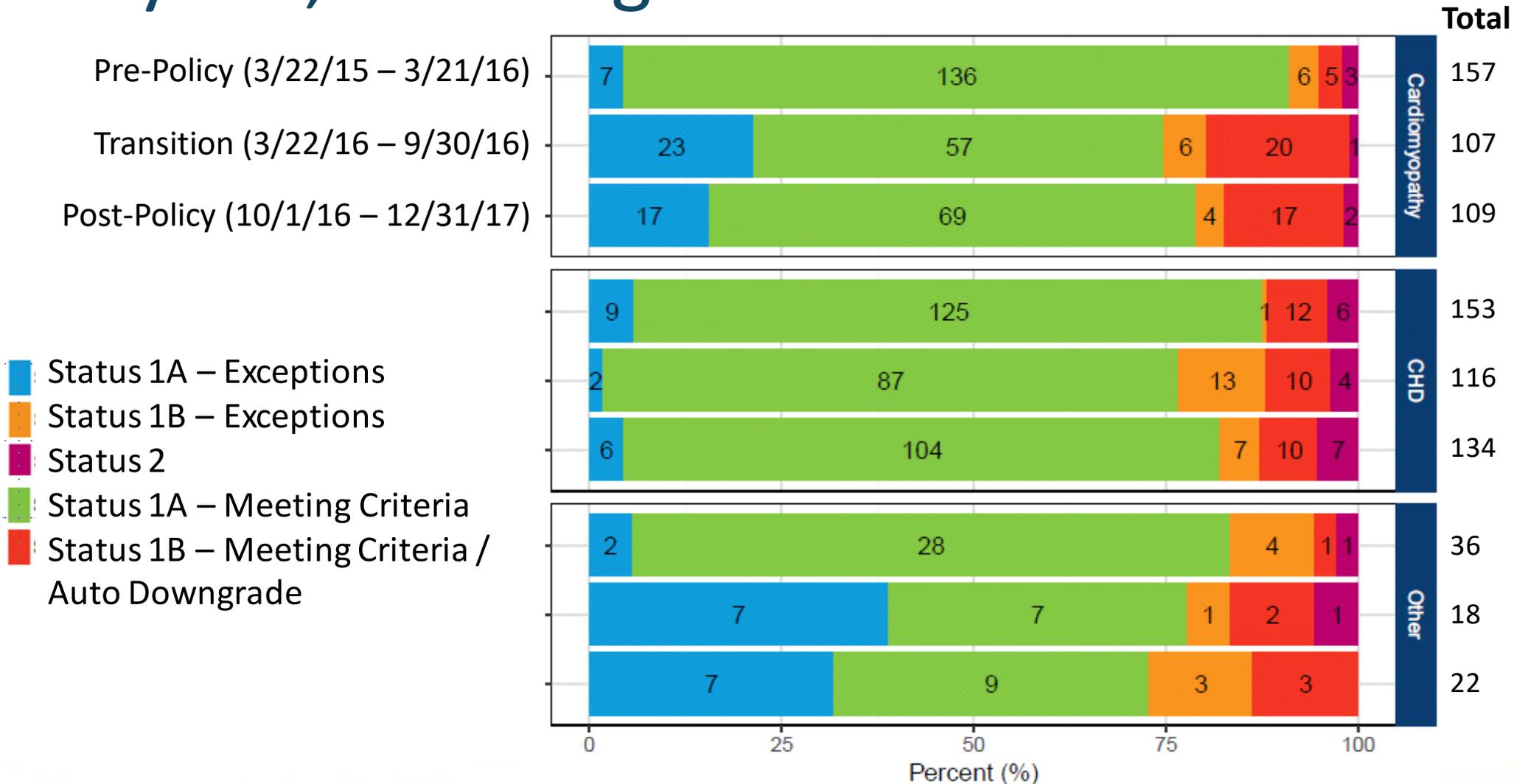
# Appeals

- Programs have the right to appeal any negative decision
- First appeal is to the same group of reviewers
- Final appeal is to a workgroup of OPTN Pediatric and Thoracic Committee members

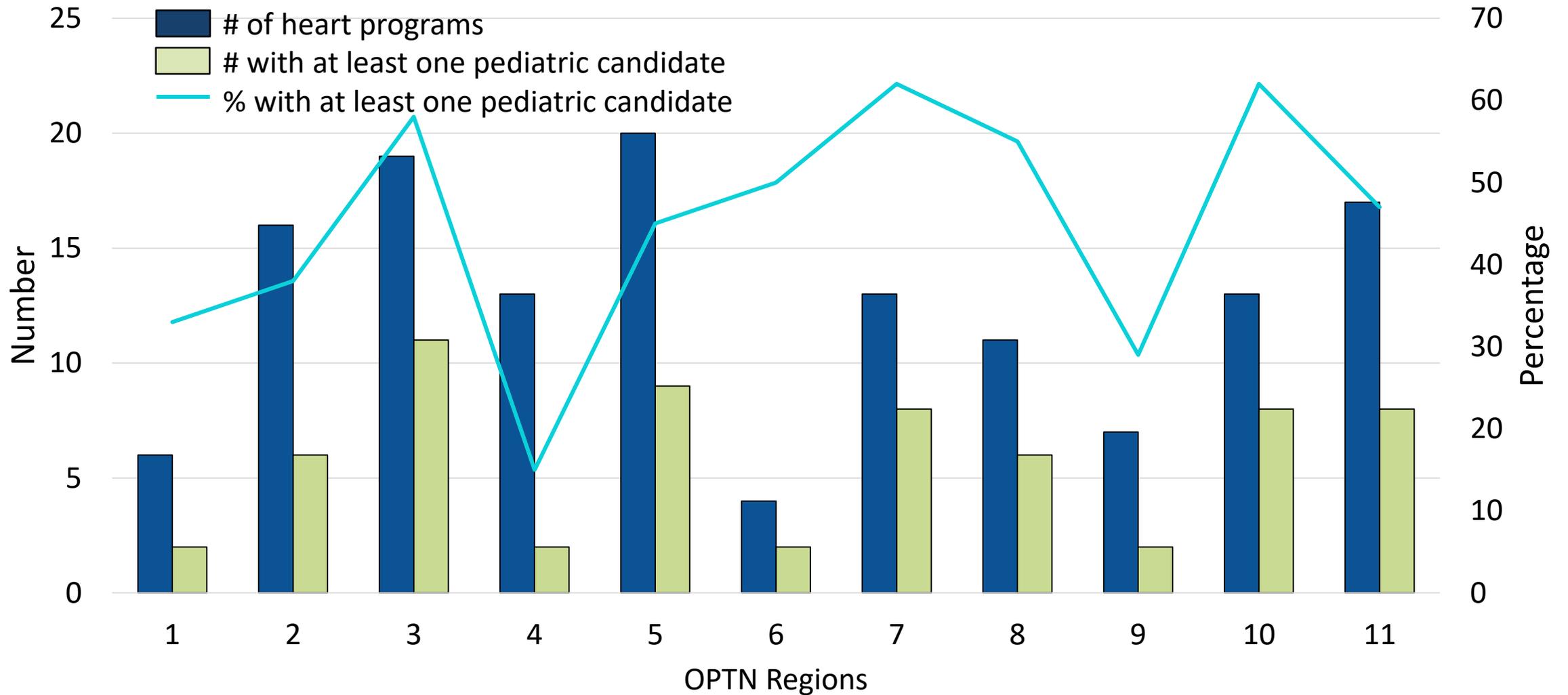
# Rationale

- Waitlist mortality rates did not decrease following implementation of new allocation system
- Increased numbers of Status 1A exceptions since the implementation of more stringent Status 1A criteria
- Variation in number of exceptions across regions

# Pediatric Heart Transplants by Exception Status, Policy Era, and Diagnosis



# Heart Programs With at Least One Pediatric Candidate



Data represent 1/1/2018 through 6/30/2019

# Feedback Requested

- Composition
- Voting
- Reviewer removal threshold

# Key Takeaways

# OPTN Thoracic Organ Transplantation Committee Update: Lung-focused Projects

# Committee Project Updates – Lung

- Problem Analysis
  - Analysis of Using an Updated Cohort in LAS
  - Consideration of New Data Elements for Potential Inclusion in Future LAS Update
- Post-implementation Review
  - Eliminate the Use of DSAs in Thoracic Distribution
  - Perfusion EVLP Policy
- Evidence Gathering
  - Continuous Distribution of Lungs

# Analysis of Using an Updated Cohort in LAS

- Current LAS coefficients based on cohort more than 10 years old
- SRTR refit models used to calculate LAS using updated cohorts
- Generally, updating model cohorts decreased LAS values slightly
- Results included changes in some covariates' coefficient signs and other covariates no longer being predictive
- Project public comment period: August – October 2020
- Any feedback on how frequently this should be updated in the future?

# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

- Concerns LAS no longer adequately captures candidates' statuses
- Continuous Distribution of Lungs Workgroup identified some potential new data elements for collections
  - Multiple years of data collection are generally required prior to analysis
  - Begin collecting in order to address LAS following completion of Continuous Distribution
- Project public comment period: August – October 2020

# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

## New data elements

- CF-specific variables, consisting of the following only
  - Any Burkholderia species
  - Massive hemoptysis
  - Hospitalized days within last year
- Diagnosis – Combined PF/COPD (CPFE)
- Diagnosis – Pleuroparenchymal fibroelastosis (PPFE)

# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

## New data elements

- REVEAL (PH) variables, consisting of the following only
  - SBP  $\geq$  110 or  $<$ 110
  - HR  $>$ 92 or  $\leq$ 92
  - BNP
  - PVR
  - Pericardial effusion on echo
- Highest FEV1 and FVC in the 12 months preceding listing
- DLCO

# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

Considering changing how values are reported

- FEV1
- O2
  - At rest, at exertion, saturation at rest and exertion
  - Allow entry of either/both L/min and/or FiO2
  - Delivery method
- HLA – require entry with option to indicate whether system should screen out donors for specific unacceptable

# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

## Removing data elements

- Percent predicted FEV1 and FVC (can be calculated using equations)
- Pre/post bronchodilator FEV1
- Prior cardiac surgery
- Pan-resistant bacterial lung infection

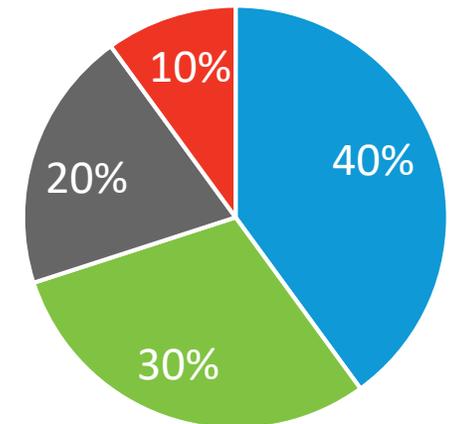
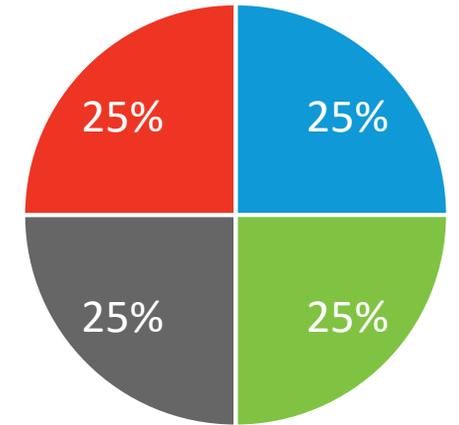
# Consideration of New Data Elements for Potential Inclusion in a Future LAS Update

- Workgroup will continue refining which new data elements to collect
- Data elements will not be considered for use in LAS until adequate data has been collected
- Please provide feedback on whether these are the right elements to consider adding

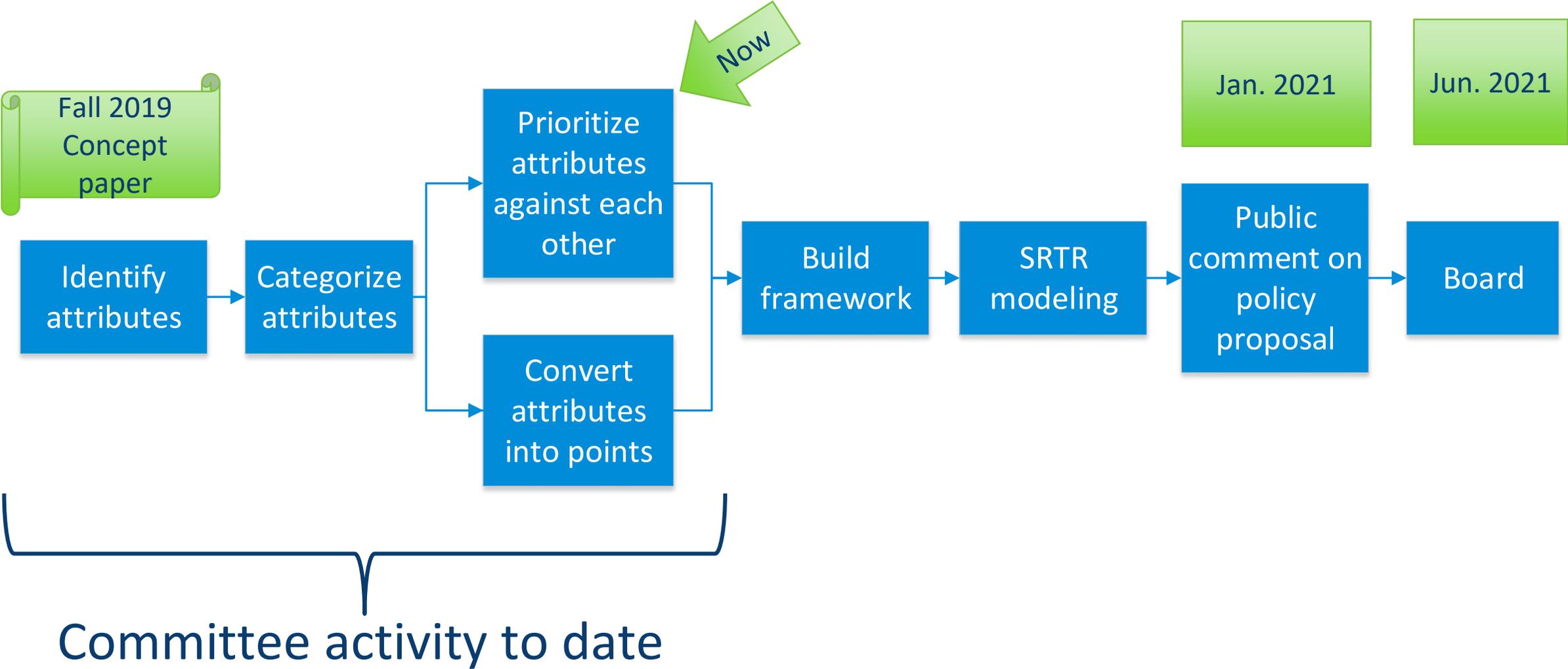
# Continuous Distribution of Lungs

*Thoracic Breakout Session*

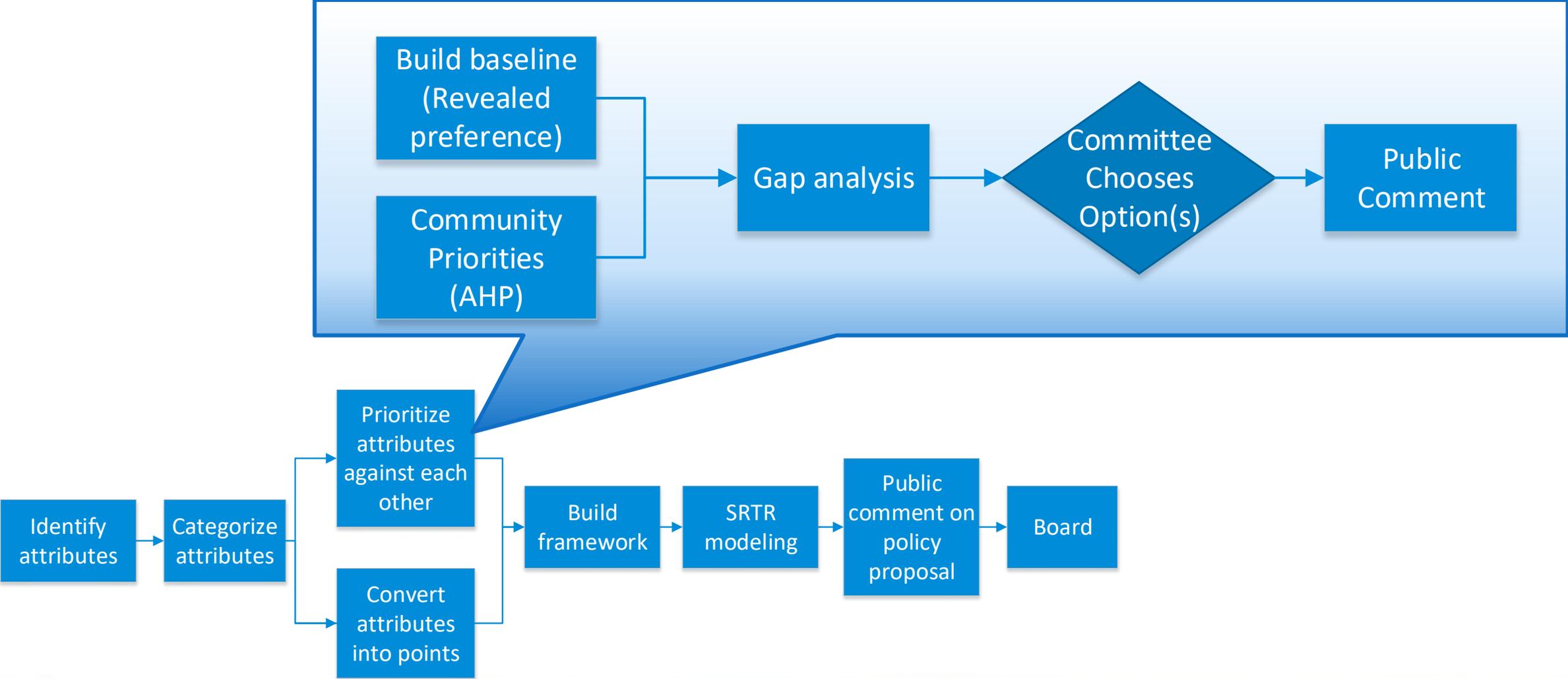
# Composite Allocation Score



# The Path Forward



# Attribute Prioritization



# Attribute Prioritization

1

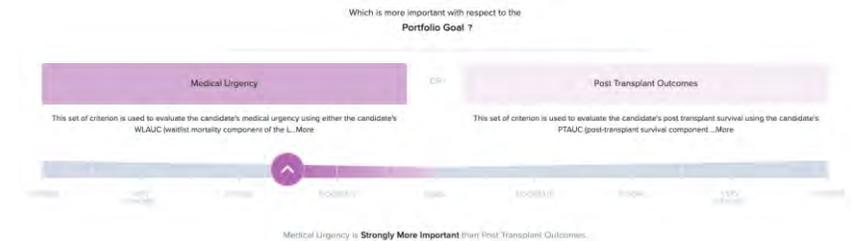
Criteria Defining



- Allocation of deceased donor, pediatric lungs
  - Medical Urgency
  - Post Transplant Outcomes
  - Reducing Biological Disadvantages in Transplant Access
  - Prior living donor
  - Candidate Age Group
  - Waiting Time
  - Travel Efficiency

2

Establishing Attribute Impact



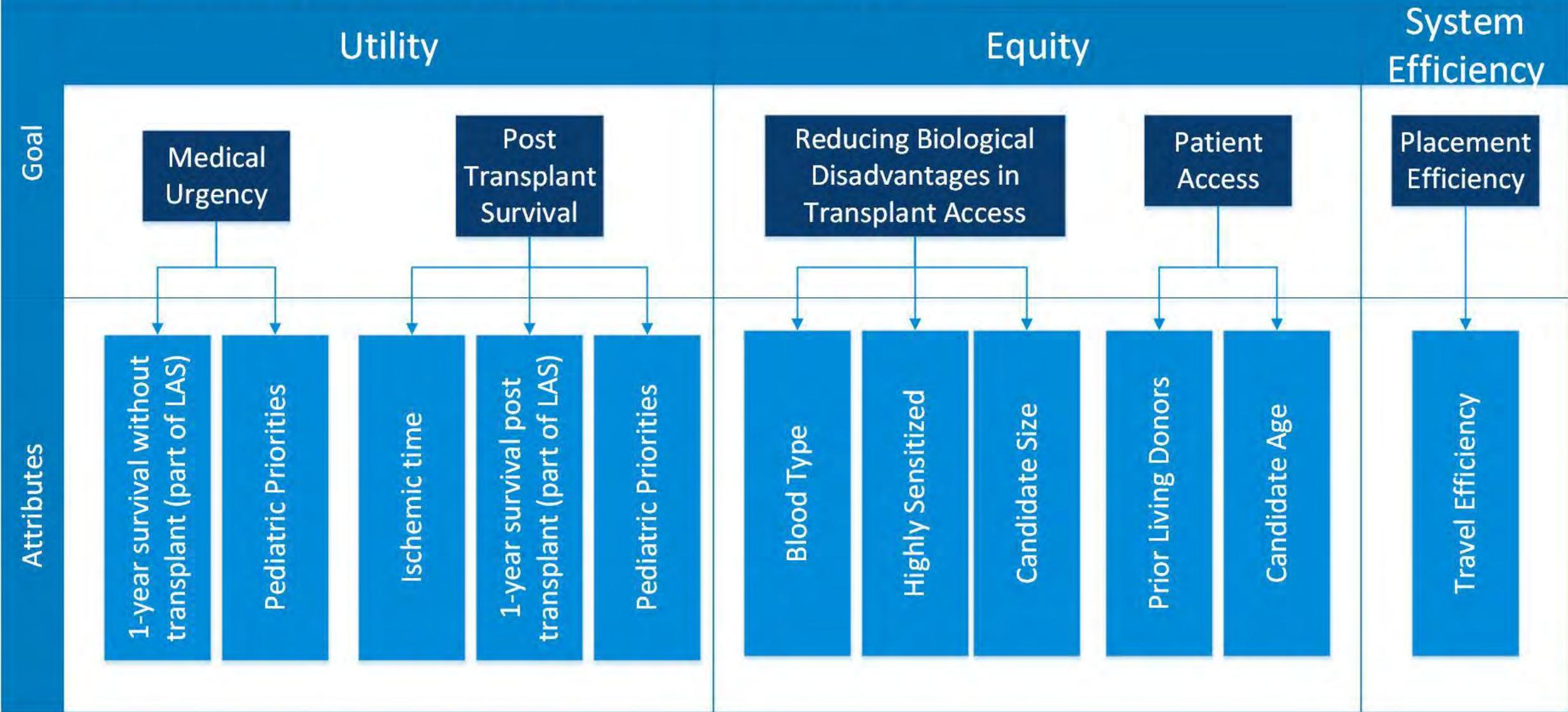
3

Attribute Weights



- 100% Allocation of deceased don...
  - 31.13% Medical Urgency
  - 16.03% Post Transplant Outcom...
  - 12.05% Reducing Biological Disa...
  - 9.87% Prior living donor
  - 20.84% Candidate Age Group
  - 4.31% Waiting Time
  - 5.77% Travel Efficiency

# Allocation of Deceased Donor Lungs



# Attributes Not Included for First Iteration

- Size matching
- Perfusion usage
- Waiting time
- Likelihood of acceptance

# Weighing Attributes

- **Clinically Weighted:**
  - Medical Urgency: LAS v Pediatric Priority
  - Post Transplant Survival: Ischemic Time, LAS, & Pediatric Priority
  - Reducing Biological Disadvantages: ABO, Sensitization, Height
- **Values Laden:**
  - Medical Urgency
  - Post Transplant Survival
  - Reducing Biological Disadvantages
  - Prior Living Donors
  - Candidate Age
  - Placement Efficiency

# Pairwise Comparison

Which is more important with respect to the **Portfolio Goal ?**

**Medical Urgency** OR **Travel Efficiency**

This set of criteria is used to award points based upon the candidate's risk of dying while waiting for a transplant using either the candidate's w...More

This criteria considers the cost of transporting an organ between the donor and transplant hospital, to prioritize candidates for whom shipping the...More

XTREME VERY STRONG STRONG MODERATE EQUAL MODERATE STRONG VERY STRONG XTREME

Medical Urgency is **Equally As Important** as Travel Efficiency.

Clear Vote

# Attribute Weights



- The results of the exercise will be compiled and analyzed by location and type of respondent
- The results and analyses will be shared with the workgroup and committee as purely advisory.
- The committee ultimately has the responsibility for developing the eventual policy proposal and will not be bound by the results of the exercise.
- During the policy development the committee is beholden to NOTA and the Final Rule.

# Next Steps

- Collect community feedback through March 31<sup>st</sup>
- Committee will review for consensus and differences by stakeholder groups
- Committee will compare results against a baseline of the current system
- Committee will discuss how to transition from current state to future state
- Policy proposal in January 2021

# Next Steps

- Watch for the post-meeting email, which will include sign in information to participate in the prioritization exercise (only if you signed in for the breakout)

# Committee Project Implementation Updates

- **Eliminate the Use of DSAs in Thoracic Distribution**
  - Replaces DSA in heart allocation policy with nautical mile distances between the transplant and donor hospitals
  - Implemented January 9, 2020
- **Modification of Lung Transplant Recipient Follow-up (TRF) Form to Include CLAD**
  - IT has initiated activities to start the implementation process
  - Implementation date being finalized

# Monitoring: Modifications to the Adult Heart Allocation System

- Four month-monitoring report is available
- Cogswell, et al, “An early investigation of outcomes with the new 2018 donor heart allocation system in the United States”
- Thoracic leadership developed response and plans submission to JHLT
  - Data submission deadlines for recipient follow-up info yet to be reached for many recipients
  - Subcommittee is currently reviewing the use of exceptions with intention of providing a guidance document addressing candidates at a Status 2 on an IABP
  - Decisions transplant programs make regarding candidate management, listing, and transplant decisions may need additional consideration

# Monitoring: Modifications to the Adult Heart Allocation System

- Future monitoring:
  - Next update will be 1-year monitoring report in March
  - Future monitoring reports at six month intervals for first 2 years and annually thereafter until 5 years
- Any questions or early feedback on the policy change?

# Monitoring: Lung Allocation Policy and Perfusion EVLP Policy

- Changes to lung allocation policy: 1 year monitoring report available on the OPTN site:  
[https://optn.transplant.hrsa.gov/media/2815/20190116\\_thoracic\\_committee\\_report\\_lung.pdf](https://optn.transplant.hrsa.gov/media/2815/20190116_thoracic_committee_report_lung.pdf)
- Next update will be 2-year monitoring report with projected release in 2020
- Perfusion EVLP policy monitoring: <https://unos.org/news/insights/will-organ-perfusion-transform-transplantation/>
- Monitoring report projected release in early 2020

# Questions

# Creating Separate OPTN Heart and Lung Committees

- Committee recommended creating new Heart and Lung Committees at their October meeting
  - These two new committees will replace the Thoracic Committee if approved
- Board of Directors considering recommendation during March 2020 meeting
  - If approved, projected implementation July 1, 2020
  - OPTN will initiate committee nominating process for new committees in April

# New Project Ideas

- What problems do you believe the OPTN Thoracic Committee should be addressing?

# Thoracic Community Engagement

- How do you want to receive updates on the work of the Thoracic Committee?

# OPEN DISCUSSION