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\textsuperscript{SM} (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

Pre-Policy (3/22/15 – 3/21/16)
- Status 1A – Exceptions: 7
- Status 1B – Exceptions: 136
- Status 2: 6
- Total: 157

Transition (3/22/16 – 9/30/16)
- Status 1A – Exceptions: 23
- Status 1B – Exceptions: 57
- Status 2: 6
- Total: 107

Post-Policy (10/1/16 – 12/31/17)
- Status 1A – Exceptions: 17
- Status 1B – Exceptions: 69
- Status 2: 4
- Total: 109

- Status 1A – Meeting Criteria: 157
- Status 1B – Meeting Criteria / Auto Downgrade: 107
- Status 2: 109
- Total: 373

- Status 1A – Exceptions: 153
- Status 1B – Exceptions: 116
- Status 2: 134
- Total: 303

- Status 1A – Meeting Criteria: 36
- Status 1B – Meeting Criteria / Auto Downgrade: 18
- Status 2: 22
- Total: 76

Note: The chart illustrates the number of pediatric heart transplants under different statuses and exception criteria during the specified policy eras.
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 proceeding 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

\[ \text{Medical urgency score} + \text{Placement efficiency score} + \text{Outcomes score} + \text{Patient access score} = \text{Patient’s Composite Allocation Score} \]

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25% 25% 25%}

OPTN
ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
The Path Forward

- Identify attributes
- Categorize attributes
- Prioritize attributes against each other
- Convert attributes into points
- Build framework
- SRTR modeling
- Public comment on policy proposal
- Board

Committee activity to date

Fall 2019 Concept paper

Jan. 2021

Jun. 2021

Committee activity to date
Attribute Prioritization

1. Identify attributes
2. Categorize attributes
3. Prioritize attributes against each other
4. Convert attributes into points
5. Build framework
6. SRTR modeling
7. Public comment on policy proposal
8. Board
9. Gap analysis
10. Committee chooses option(s)
11. Public comment

Build baseline (Revealed preference)
Community Priorities (AHP)
Attribute Prioritization

1. Criteria Defining

2. Establishing Attribute Impact

3. Attribute Weights

OPTN
ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
Allocation of Deceased Donor Lungs

**Utility**
- Medical Urgency
- Post Transplant Survival
- Ischemic time
- 1-year survival post transplant (part of LAS)
- Pediatric Priorities

**Equity**
- Reducing Biological Disadvantages in Transplant Access
- Blood Type
- Highly Sensitized
- Candidate Size
- Prior Living Donors
- Candidate Age

**System Efficiency**
- Placement Efficiency
- Travel Efficiency

OPTN ORGAN PROCUREMENT AND TRANSPANTATION NETWORK
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...More

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

Medical Urgency is Equally As Important as Travel Efficiency.

Clear Vote
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 31st
- 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
- 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

  - Next update will be 2-year monitoring report with projected release in 2020

  - 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