

### **Public Comment Proposal**

# **Establish Continuous Distribution of Lungs**

**OPTN Lung Transplantation Committee** 

Prepared by: Elizabeth Miller UNOS Policy and Community Relations Department

### **Contents**

| Executive Summary                                    | 2   |
|--|-----|
| Purpose  | 4   |
| Background   | 4   |
| Composite Allocation Score Relative Weights          | 9   |
| Rating Scales  | 18  |
| Other Considerations                                 | 35  |
| Update Schedule                                      | 35  |
| Waiting Time   | 36  |
| Multi-Organ Allocation                               | 37  |
| Exceptions   | 40  |
| Potential Impact on Select Patient Populations       | 42  |
| Policy Structure                                     | 55  |
| NOTA and Final Rule Analysis                         | 57  |
| Implementation Considerations                        | 59  |
| Member and OPTN Operations                           | 59  |
| Projected Fiscal Impact                              | 60  |
| Post-implementation Monitoring                       | 61  |
| Member Compliance                                    | 61  |
| Policy Evaluation                                    | 62  |
| Conclusion   | 63  |
| Appendix A: Lung Review Board Operational Guidelines | 135 |
| Appendix B: Glossary of Terms                        | 138 |



# **Establish Continuous Distribution of Lungs**

Affected Policies: 1.2: Definitions

3.6.A: Waiting Time for Inactive Candidates 5.10.C: Other Multi-Organ Combinations

6.6.F: Allocation of Heart-Lungs

6.6.F.i: Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old 6.6.F.ii: Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old

10: Lung Allocation (and all subsections)

Sponsoring Committee: Lung Transplantation

Public Comment Period: August 3, 2021 – October 1, 2021

### **Executive Summary**

This proposal would make lungs the first organ to move to the new system of continuous distribution as part of a larger shift in organ allocation that is planned ultimately to include all organs. Continuous distribution was chosen as the system "best suited for future OPTN organ allocation policies" to support the goals listed in the Final Rule, the mission of the OPTN, and the ethical underpinnings of allocation of a scarce, life-saving resource by the OPTN Board of Directors.¹ Lung is the first, but will not be the last organ to experience this metamorphosis, removing hard boundaries and replacing them with a system that considers a host of individual factors as part of a single composite allocation score for each candidate.²

This proposal is expected to improve upon current lung allocation policy by reducing waitlist deaths for lung candidates while also decreasing the percentage of organ recoveries that require flying, reducing geographic disparities, and increasing access for pediatric candidates through smarter distribution.

The Lung Transplantation Committee (Committee)<sup>3</sup> proposes using a continuous distribution framework for lung allocation; in which candidates are ranked on the match run according to a composite allocation score (CAS) that incorporates:

- Candidate's expected 1 year waiting list mortality
- Candidate's 5 year post-transplant survival measures
- Candidate's blood type

<sup>&</sup>lt;sup>1</sup> OPTN Policy Notice, Frameworks for Organ Distribution, December 4, 2018.

https://optn.transplant.hrsa.gov/media/2789/geography\_policynotice\_201901.pdf (Accessed June 13, 2021).

<sup>&</sup>lt;sup>2</sup> The OPTN Board of Directors adopted the framework of Continuous Distribution for future organ allocation and directed the OPTN Lung Transplantation Committee to "move toward the Continuous Distribution allocation framework as they consider future amendments and improvements to their respective allocation policies." However, the Board resolution does not prescribe that this particular proposal must be adopted. This proposal should be evaluated on its merits. OPTN Policy Notice, Frameworks for Organ Distribution, December 4, 2018.

https://optn.transplant.hrsa.gov/media/2789/geography\_policynotice\_201901.pdf (Accessed June 13, 2021).

<sup>&</sup>lt;sup>3</sup> The Lung Transplantation Committee was official created on July 1, 2020, and work before that time was performed by the OPTN Thoracic Organ Transplantation Committee. "Committee" in this proposal means either the Thoracic Committee or the Lung Committee, depending on the point in time. OPTN, Notice of OPTN Policy, Bylaw, and Guidelines Changes, *Creation of OPTN Heart and Lung Committees*. <a href="https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf">https://optn.transplant.hrsa.gov/media/3721/thoracic-split-policy-notice-march-2020.pdf</a> (Accessed June 11, 2021).

- Candidate's CPRA
- Candidate's height
- Whether a candidate is under 18 years old
- Whether the candidate is a prior living donor
- Travel efficiency
- Proximity efficiency

Below, the Committee outlines how each of these factors will be used, and to what degree. In order to ensure that these changes work within the system, the Committee also proposes related changes to the Lung Review Board, and allocation of heart-lung, lung-kidney, and lung-liver combinations.



### **Purpose**

This proposal will align lung allocation policy with community, ethical, and regulatory requirements, goals and medical advancements, while considering each candidate holistically. It moves lung allocation into a new era of allocation, continuous distribution, to remove hard boundaries in lung allocation, and create a smarter allocation system, improving adaptability and consistency across organs.

#### **Moving Beyond Separate Classifications**

As part of the transition to a single, unified score to rank candidates on the lung list, the current system of classifications and separate allocation orders based on donor characteristics, so called "hard boundaries," would be dissolved. Candidates are currently classified and ranked in different order depending on the age of the lung donor (under 18 or at least 18). This change would remove that distinction and lungs from all donors would be allocated in the same way, with the same scoring system and ordering approach applied for each donor. This allows the system to provide more equity for patients and more transparency in the allocation system, while allowing more efficiency in allocation policy changes.

Further, within the current allocation system, each list is divided into 36 classifications such as "candidates who are at least 12 years old, with an identical blood type to the donor within 250NM", which comes before "candidates who are at least 12 years old, with a compatible blood type to the donor within 250NM". Once grouped in these classifications, the current system ranks candidates individually. This "hard boundary" does not allow the flexibility of allowing a candidate with a compatible blood type who is much more medically urgent, and possibly only 251 NM away from the donor to move ahead of a single candidate with an identical blood type who is 249 NM away. This proposed system would incorporate exactly that sort of nuance and flexibility by removing such hard boundaries.

Candidate screening criteria<sup>4</sup> become more important in a continuous distribution system for those situations where an adult candidate would not want to accept a lung from a very small donor, but the tradeoff is that very short adults are placed appropriate to their need when a large 17-year-old donates lungs. Similarly, a 17-year-old would keep their pediatric points whether the donor was under or over 18, because the specific cutoff for donor age is not as relevant as candidate factors for determining candidate ranking.

### **Background**

In December 2018, the OPTN Board of Directors selected continuous distribution as the preferred organ distribution framework for all organs. <sup>5</sup> This framework will replace the current classification-based

<sup>&</sup>lt;sup>4</sup> Screening criteria help achieve safe and efficient matching of donor organs to transplant candidates. For each candidate, transplant programs enter certain mandatory and optional information to ensure that offers are only received from donors that are likely to be acceptable for the candidate, based on both the donor and candidate factors. For example, a transplant program can enter a potential donor's height range that would be acceptable for the transplant program's candidate. If a donor organ becomes available from a donor that is outside of the range, the candidate will be screened off that donor's match run and the offer will not be made to that particular candidate because the transplant program has already indicated that it would not accept a donor outside of the range.

<sup>&</sup>lt;sup>5</sup> OPTN Policy Notice, Frameworks for Organ Distribution, December 4, 2018. https://optn.transplant.hrsa.gov/media/2789/geography\_policynotice\_201901.pdf (Accessed June 13, 2021).

allocation system with a points-based allocation system. The goal of this framework is more equity for patients; more transparency into the allocation system; and more efficiency in developing organ allocation policies. While the Committee and this proposal focuses on lung allocation, each organ-specific committee will evaluate how to apply this framework to their organ-specific allocation policies.

Lung was selected as the first organ to make the change to the continuous distribution framework in part because lung allocation already includes formulaic measures of both waiting list survival and post-transplant outcomes, which provides a pre-existing foundation for the new composite allocation score. The current lung allocation score (LAS) is derived from two included scores, waiting list urgency measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list, and post-transplant survival measure, which is the expected number of days a candidate will live during the first year post-transplant.<sup>6</sup> As part of the move to this new framework, the Committee separated out the waitlist measure and the post-transplant measure and considered anew what the appropriate balance should be between these two factors as they considered how to balance all of the component parts of the new lung composite allocation score.

The Committee shared information and solicited input from a variety of stakeholders via traditional and non-traditional methods and broader outreach over two years, in order to ensure adequate input and data analysis.

#### **General education**

To educate the community about continuous distribution, a presence on the OPTN website was established to explain concepts and plans for development. Progress specific to the development of lung continuous distribution was shared on its own OPTN webpage and included:

#### 2019

Concept paper on the continuous distribution of lungs<sup>7</sup>

#### 2020

- Request for feedback and update on work that had been completed so far<sup>8</sup>
- Results of community feedback on priorities that was provided through a prioritization exercise<sup>9</sup>
- Results of an analysis to reveal the preferences inherent in the current lung allocation system<sup>10</sup>
- An interactive tool for visualizing what a match would look like under continuous distribution<sup>11</sup>

<sup>&</sup>lt;sup>6</sup> OPTN Policy 10.1.5 The LAS Calculation.

<sup>&</sup>lt;sup>7</sup> Concept Paper, *Continuous Distribution of Lungs*, OPTN Thoracic Organ Transplantation Committee. Public Comment Period August 2, 2019-October 2, 2019. https://optn.transplant.hrsa.gov/media/3111/thoracic\_publiccomment\_201908.pdf.

<sup>&</sup>lt;sup>8</sup> OPTN Request for Feedback, Update on the Continuous Distribution of Organs Project, OPTN Lung Transplantation Committee. Public Comment Period August 4, 2020-October 1, 2020.

https://optn.transplant.hrsa.gov/media/3932/continuous\_distribution\_lungs\_concept\_paper\_pc.pdf.

<sup>&</sup>lt;sup>9</sup> Continuous Distribution of Lungs, Summer 2020 Prioritization Exercise – Community Results, October 12, 2020.

https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf.

<sup>&</sup>lt;sup>10</sup> A Revealed Preference Analysis to Develop Composite Scores Approximating Lung Allocation Policy in the U.S., Darren Stewart, Dallas Wood, James Alcorn, Erika Lease, Michael Hayes, Brett Hauber and Rebecca Goff, BMC Medical Informatics and Decisions Making. January 6, 2021.

<sup>11</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

#### 2021

- Results from the first round of SRTR modeling<sup>12</sup>
- Results from modeling impact of 5 year post-transplant outcomes<sup>13</sup>
- Results from the second round of SRTR modeling<sup>14</sup>

This proposal does not attempt to repeat the background content contained in these earlier publications, but to set forth the specific changes to existing lung allocation policy proposed by the Committee and their rationale.

Regularly shared progress with the community, provided opportunities for feedback, and input regarding continuous distribution:

- at Patient Affairs Committee meetings,
- at regional meetings in all 11 regions,
- in targeted emails to the lung community and with professional societies including:
  - o the American Society of Transplantation,
  - American Society of Transplant Surgeons,
  - National Association of Transplant Coordinators,
  - Association of Organ Procurement Organizations,
  - International Society for Heart and Lung Transplantation,
  - o American College for Chest Physicians,
  - American Association of Transplant Surgeons, and
  - Society of Transplant Surgeons;
- and to patient and donor family groups, including:
  - o the Alpha-1 Foundation,
  - American Lung Association,
  - Children's Interstitial & Diffuse Lung Disease Foundation,
  - Children's Organ Transplant Association,
  - COPD Foundation,
  - Cystic Fibrosis Foundation,
  - Donate Life America,
  - Emphysema Foundation for Our Right to Survive,
  - Hermansky-Pudlak Syndrome Network, Inc.,
  - Histiocytosis Association,
  - Lung Transplant Foundation,
  - Lymphangiomatosis & Gorham's Disease Alliance,
  - Pulmonary Alveolar Proteinosis Foundation,
  - Pulmonary Fibrosis Foundation,
  - Pulmonary Hypertension Association,
  - Second Wind: Lung Transplant Association Inc.,
  - o the Lymphangioleiomyomatosis Foundation,
  - o and the Transplant Recipients International Organization.

<sup>&</sup>lt;sup>12</sup> SRTR, Continuous Distribution Simulations for Lung Transplant, Data Request ID# LU2020\_05, February 12, 2021. https://optn.transplant.hrsa.gov/media/4450/lu2020\_05\_cont\_distn\_srtr\_1.pdf.

<sup>&</sup>lt;sup>13</sup> SRTR The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant, February 17, 2021. (Accessed June 18, 2021) https://optn.transplant.hrsa.gov/media/4675/lu\_posttx\_5y\_2\_2021.pdf.

<sup>&</sup>lt;sup>14</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf



Additionally, leaders of Heart Transplantation, Liver and Intestine Transplantation, Kidney Transplantation, Pancreas Transplantation, Vascularized Composite Allocation Transplantation, Policy Oversight, and Multi-Organ Transplantation committees were consulted regarding several areas where decisions would be best made in alignment across organs, such as providing points for prior living donors.

#### AHP prioritization exercise

The Committee chose the Analytical Hierarchy Process (AHP) prioritization exercise specifically for its ability to be used effectively by other health care groups to involve patients in clinical decisions. The AHP exercise is a method for eliciting and quantifying values judgments from participants.

The exercise was promoted on the OPTN website and directly to the Patient Affairs Committee, lung community (which included health care administrators, organ donation and transplantation professionals, patients, and interested public), Regional Meeting attendees in all 11 regions, professional societies and patient organizations via targeted emails and presentations. These encouraged the recipients not only to participate in the exercise, but also to pass along the information and encourage participation by others, such as their transplant patients and families. The exercise was available for participation from August 31, 2019 to October 1, 2020, and 196 individuals submitted responses. 15

#### **Composite Allocation Score Regulatory Alignment**

The National Organ Transplantation Act (NOTA) and the OPTN Final Rule contain multiple requirements for organ allocation policies. The Committee proposes a composite score than combines five different scores. These different scores align with the requirements found in NOTA and the OPTN Final Rule.

Error! Reference source not found. shows how these five scores combine into a composite score. A description of each score follows **Error! Reference source not found.**.

Patient's Post-Biological Transplant Efficiency Composite Disadvantages Access Allocation **Outcomes** Score Score Score

Score

Figure 1: Components of Composite Allocation Score

Waiting list urgency score: The Final Rule requires the OPTN to rank candidates from most to least medically urgent through "objective and measurable medical criteria," and to develop allocation policies in part to achieve the "best use of donated organs." OPTN policies use several different approaches to prioritize candidates based upon their medical urgency: model for end-stage liver disease (MELD), pediatric model for end-stage liver disease (PELD), heart statuses, lung pediatric priorities<sup>18</sup>, etc. A portion of the lung allocation score (LAS) is the predicted waiting list survival, or medical urgency of lung candidates. This proposal uses the

Waiting

List

Urgency

Score

Score

<sup>&</sup>lt;sup>15</sup> Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf.

<sup>&</sup>lt;sup>16</sup> 42 C.F.R. §121.8(b)(2).

<sup>17</sup> Ibid. at §121.8(a)(2).

<sup>&</sup>lt;sup>18</sup> In lung allocation, pediatric priorities are akin to statuses in other organs.

- medical urgency calculation that is currently part of the LAS to determine the waitlist urgency score, one of the 5 goal-level scores that together form new composite allocation score.
- Post-transplant outcomes score: The Final Rule requires allocation policies be designed to "avoid futile transplants."<sup>19</sup> This is currently part of the LAS score, and the Committee proposes treating this component separately as the post-transplant outcomes score.
- *Biological disadvantages score*: The Final Rule requires allocation policies be designed to "promote patient access to transplantation." This policy uses scores to make access more equitable based on candidate blood type, calculated panel reactive antibodies (CPRA), and height.
- Patient access score: The Final Rule requires allocation polices be designed to "promote patient access to transplantation"<sup>21</sup> and "recognize the differences in health and in organ transplantation issues between children and adults ... and adopt criteria, polices, and procedures that address the unique health care needs of children."<sup>22</sup> OPTN policies use several approaches for this purpose; this proposal provides additional access to transplantation for pediatric candidates and priority for prior living donors.
- Efficiency score: The Final Rule requires allocation policies be designed to "promote the efficient management of organ placement." <sup>23</sup> "Efficient" organ placement can be evaluated in multiple ways. For example, in recent years, much attention has been given to the number of organs transported by air travel given the potential for greater costs logistical challenges with air versus ground travel. The Final Rule contemplates incorporating into allocation policies consideration of a candidate's place of residence or place of listing if required to achieve other requirements of the Final Rule, such as to achieve efficient organ placement or to avoid "wasting" organs. <sup>24, 25</sup> The Committee therefore proposes including measures of travel efficiency and proximity efficiency. <sup>26</sup>

Combining multiple scores together allows consideration of all of these goals in organ allocation policies. It will also promote transparency in the similarities and differences between the roles of each score across organs. Finally, by constructing the composite score around the requirements of the OPTN Final Rule, the system will clarify the alignment with the OPTN Final Rule.

<sup>&</sup>lt;sup>19</sup> 42 C.F.R. §121.8(a)(5).

<sup>&</sup>lt;sup>20</sup> Ibid.

<sup>&</sup>lt;sup>21</sup> Ibid.

<sup>&</sup>lt;sup>22</sup> 42 C.F.R. §274(b)(2)(M).

<sup>&</sup>lt;sup>23</sup> 42 C.F.R. §121.8(a)(5).

<sup>&</sup>lt;sup>24</sup> 42 C.F.R. §121.8(a)(8).

<sup>&</sup>lt;sup>25</sup> The Federal Register notice related to the development of the OPTN Final Rule noted the connection between the possibility of "wasting organs" as a result of excessive transportation times and efficient management of organ allocation. "Broad geographic sharing should not come at the expense of wasting organs through excessive transportation times. Efficient management of organ allocation will sometimes dictate less transportation when the highest-ranking patient can wait a day or two for the next available organ. Sound medical judgment must be exercised before a final decision on whether to transplant a particular organ into a particular patient." 63 FR 16315 (1998).

<sup>&</sup>lt;sup>26</sup> The use of the candidate's "place of listing" is only used in order to promote efficient management of organ placement. This limitation is in line with the requirement that allocation policies "shall not be based on the candidate's place of residence of place of listing, except to the extent required by paragraphs ()(1)-(5) of this section.", which paragraphs include that allocation policies shall "promote the efficient management of organ placement". 42 C.F.R. §121.8.a.



### **Composite Allocation Score Relative Weights**

This proposal would replace the current lung allocation system that places candidates in classifications, and then ranks the candidates within each classification. The new system would assign each lung candidate a lung composite allocation score (CAS) and rank the lung match according to that composite score, offering to candidates with the highest score first. The CAS would include five main goals, and each includes sub-parts, called attributes as outlined in **Figure 2**.

Efficiency Medical Post-Transplant Biological **Patient Access** Promoting the Urgency Outcomes Disadvantages Efficient **Promoting Patient** Prioritizing Medically Improving Post Management of the Reducing Biological Access Organ Placement **Urgent Candidates** Transplant Outcomes Disadvantages System Travel Post-Blood Type Pediatrics Waiting List Efficiency Transplant Survival Outcomes Prior Living Proximity **CPRA** Efficiency Donors Height

Figure 2: Scores by Goals and Attributes

The maximum total composite allocation score available for any candidate is 100, and each goal has a specific weight within that total. The weight determines the maximum score for that goal, or the percentage of the potential total for each goal. **Figure 3** shows the weight the Committee proposes assigning to each goal.

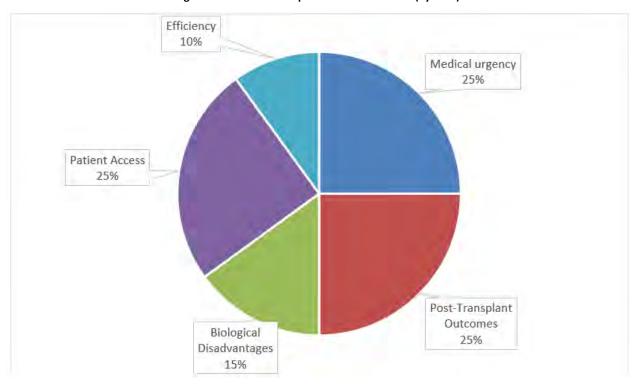


Figure 3: Percent of Composite Allocation Score (by Goal)

Within each goal, the attributes that contribute to that total also have a maximum number of points, or percentage of the potential total for that attribute based on the values of the community. **Figure 4** shows the weights proposed for each specific attribute.

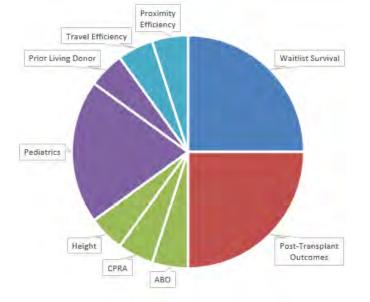


Figure 4: Percent of Composite Allocation Score (by Attribute)

| Attribute                | Weight |
|--------------------------|--------|
| Waiting list Survival    | 25%    |
| Post-Transplant Survival | 25%    |
| Candidate Biology        | 15%    |
| ABO                      | 5%     |
| CPRA                     | 5%     |
| Height                   | 5%     |
| Patient Access           | 25%    |
| Pediatric                | 20%    |
| Prior Living Donor       | 5%     |
| Efficiency               | 10%    |
| Travel Efficiency        | 5%     |
| Proximity Efficiency     | 5%     |
|                          |        |

The relative weights were developed by using multiple novel methods to identify the relative importance placed on each attribute. These included:

Analytical Hierarchy Process (AHP) AHP is a prioritization exercise that allowed members of the public, members of the transplant community, and members of many OPTN committees to contribute their value judgments by ranking pairs of attributes relative to one another. This was chosen as an approachable way for a broader selection of people to provide detailed feedback. This is described in greater detail in the *Continuous Distribution of Lungs: Summer 2020 Prioritization Exercise – Community Results* report.<sup>27</sup> The results from the 196 participants in that exercise showed an overall preference for prioritizing pediatric candidates, post-transplant survival, waiting list survival, and factors in a candidate's biology that make them hard to match. Generally, improving efficiency and ensuring access for prior living donors ranked lower, except among respondents associated with organ procurement organizations (OPOs).

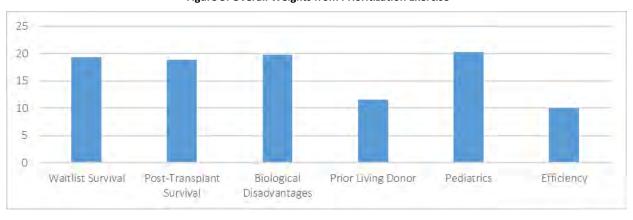


Figure 5: Overall Weights from Prioritization Exercise

**Revealed Preference Analysis (RPA)** The Committee also considered an analysis of the current system, and how it would translate into a points-based system like continuous distribution, conducted in conjunction with the Research Triangle Institute. <sup>28</sup> This was chosen as an additional way to allow the Committee to compare the degree of changes contemplated compared to the current system while changing the basic framework dramatically since the current system had not been evaluated from that perspective before.

In that analysis, proximity was the primary factor, with medical priority (measured by LAS score, a combination of waiting list urgency and post-transplant outcomes) second, candidate blood type third, and candidate age the least important, when keeping separate allocation systems for adult donors and pediatric donors. In the adult donor model, medical priority made up 10% of the score; candidate age made up 4% of the score; proximity made up 81% of the score; and blood type made up 5% of the score. <sup>29</sup> Notably, these weights were very different from those revealed as the apparent preference of the transplant community and policy makers through the AHP exercise.

11 Public Comment Proposal

. . .

<sup>&</sup>lt;sup>27</sup> https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf

<sup>&</sup>lt;sup>28</sup> Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf
<sup>29</sup> *Ibid.* 

**Thoracic Simulated Allocation Model (TSAM)** The Scientific Registry of Transplant Recipients (SRTR) provided simulation modeling of specific potential policy scenarios. Organ-specific simulated allocation models are typically used to evaluate the expected impact of significant allocation changes, and results are discussed in further detail below.

**Optimization Analysis** Researchers from the Massachusetts Institute for Technology (MIT) applied artificial intelligence and machine learning to a dataset from the TSAM to allow for optimization for specific outcomes.<sup>30</sup> This was similar to earlier analyses the researchers did with kidney and liver allocation.<sup>31</sup> Particularly useful for the Committee's deliberation, this analysis produced visualizations showing the relative impact of changes to a specific weight to certain variables.

**Sensitivity Tool** The OPTN developed a new, interactive dashboard to allow the Committee and the public to see the effect of specific changes on sample match runs as they adjusted individual pieces of the overall policy. The tool is publically available at

https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home, and readers are encouraged to use it to evaluate the impact of these proposed changes.

For a view of the Committee work so far and the results published so far, please see <a href="https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution/continuous-distribution-lung/">https://optn.transplant.hrsa.gov/governance/key-initiatives/continuous-distribution-lung/</a>.

#### **Deliberative Process**

The Committee modeled four scenarios in the first round of TSAM modeling. The Committee chose to model two versions closest to the weights preferred in the AHP prioritization exercise. The first weighs 1-year waitlist survival and 1-year post-transplant outcomes 2:1, the same relative weight as the current LAS system. The second scenario changes to 1:1, or equal weighting between 1-year waitlist survival and 1-year post-transplant outcomes, to simulate the impact of the preference expressed through the AHP exercise.

The third scenario was used to compare the impact of placing more weight on proximity, since the current system is primarily based on proximity, as match runs sort first on candidates within a specified distance (250 nautical miles of the donor) before sorting the candidates on any other factors. The RPA showed that the current weight placed on geographic proximity is more than 80%.<sup>32</sup>

<sup>&</sup>lt;sup>30</sup> OPTN Lung Transplantation Committee, Meeting Summary, March 18, 2021. (Accessed June 28, 2021) <a href="https://optn.transplant.hrsa.gov/media/4549/20210318\_lung\_meeting\_summary.pdf">https://optn.transplant.hrsa.gov/media/4549/20210318\_lung\_meeting\_summary.pdf</a>.

<sup>&</sup>lt;sup>31</sup> Dimitris Bertsimas, Vivek F. Farias, Nikolaos Trichakis, (2013) Fairness, Efficiency, and Flexibility in Organ Allocation for Kidney Transplantation. Operations Research 61(1):73-87. <a href="https://doi.org/10.1287/opre.1120.1138">https://doi.org/10.1287/opre.1120.1138</a>.

Dimitris Bertsimas, Theodore Papalexopoulos, Nikolaos Trichakis, Yuchen Wang, Ryutaro Hirose, Parsia A. Vagefi, Balancing Efficiency and Fairness in Liver Transplant Access: Tradeoff Curves for the Assessment of Organ Distribution Policies, May 2020, Transplantation, Volume 104, Number 5.

<sup>&</sup>lt;sup>32</sup> Darren E. Stewart , Dallas W. Wood , James B. Alcorn , Erika D. Lease , Michael Hayes , Brett Hauber and Rebecca E. Goff, A revealed preference analysis to develop composite scores approximating lung allocation policy in the U.S., January 6, 2021. https://optn.transplant.hrsa.gov/media/4317/2021-revealed-preference-analysis.pdf

The final scenario evaluated placing more weight on the candidate biology factors, since these were the most important factor to respondents in the AHP exercise, where it was given approximately 20% priority.<sup>33</sup>

Table 1: Modeled Weights by Goal and Attribute (TSAM round 1)34

| Component                | 2.1<br>LAS | 1.1<br>LAS | Proximity<br>Preference | Candidate Biology<br>Preference |
|--------------------------|------------|------------|-------------------------|---------------------------------|
| Waitlist Survival        | 28%        | 21%        | 14%                     | 14%                             |
| Post-Transplant          | 14%        | 21%        | 14%                     | 14%                             |
| Outcomes                 |            |            |                         |                                 |
| Biological Disadvantages | 17%        | 17%        | 11%                     | 40%                             |
| ABO                      | 5.6%       | 5.6%       | 3.6%                    | 13.3%                           |
| CPRA                     | 5.6%       | 5.6%       | 3.6%                    | 13.3%                           |
| Height                   | 5.6%       | 5.6%       | 3.6%                    | 13.3%                           |
| Patient Access           | 35%        | 35%        | 21%                     | 21%                             |
| Pediatric                | 31%        | 31%        | 20%                     | 20%                             |
| Prior Living Donor       | 4%         | 4%         | 1%                      | 1%                              |
| Efficiency               | 6%         | 6%         | 40%                     | 11%                             |
| Travel Efficiency        | 3%         | 3%         | 20%                     | 5.5%                            |
| Proximity Efficiency     | 3%         | 3%         | 20%                     | 5.5%                            |

While the scenarios were being modeled, the Committee chose to expand the post-transplant outcomes measure to include outcomes predicted out to 5 years, rather than the one-year measure included in the first request.<sup>35</sup> This decision was based on analysis provided to the Committee by the SRTR of the reliability of predicting 5-year outcomes.<sup>36</sup> The Committee also considered analysis of the expected impact on candidates by diagnosis and age, among other stratifications, and compared those to their clinical experience.<sup>37</sup> The 5-year outcomes have a similar level of confidence to 1-year outcomes, while allowing for consideration of a longer period of outcomes and greater stratification of utility of the transplants.<sup>38</sup> Additionally, the 5-year outcomes address a concern that was voiced in the comments provided with the AHP exercise that 1-year outcomes are too short-term to be a measure of long-term survival, and the long-term survival is more important as a measure of utility to include in the composite allocation score.<sup>39</sup>

The Committee submitted a second continuous distribution modeling request, with an additional six scenarios. In the second request, the Committee chose to compare again relative weights between

<sup>&</sup>lt;sup>33</sup> Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf.

<sup>&</sup>lt;sup>34</sup> SRTR Continuous distribution simulations for lung transplant, Data Request ID#: LU2020\_05. February 12, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4450/lu2020 05 cont distn srtr 1.pdf.

<sup>&</sup>lt;sup>35</sup> OPTN Lung Transplantation Committee *Meeting Summary*, March 18, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4549/20210318 lung meeting summary.pdf.

<sup>&</sup>lt;sup>36</sup> SRTR *The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant,* February 17, 2021.

<sup>&</sup>lt;sup>37</sup> Ibid.

<sup>&</sup>lt;sup>38</sup> Ibid.

<sup>&</sup>lt;sup>39</sup> Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf.



waiting list survival and post-transplant outcomes, this time using the 5-year post-transplant outcomes measure.<sup>40</sup>

After reviewing the results of the first modeling request, the Committee also considered optimization visualizations. For any two attributes within the continuous distribution model, one can evaluate the impact on one attribute of changing the point assignment for the other. For example, if all else is equal between an adult candidate and a pediatric candidate, how much more medically urgent would an adult candidate have to be in order to be ranked above a pediatric candidate? The Committee looked at curves that showed how this changes, including the curve below in *Figure 6* to focus in on where the most benefit could be gained from changes to the weight placed on efficiency.

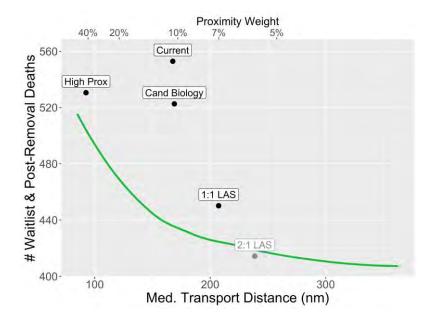


Figure 6: Impact of Changes in the Proximity Weight on Combined Waitlist and Post-Transplant Deaths<sup>43</sup>

In **Figure 6**, the green line represents the relationship between changes to the Efficiency weight (labeled here as "Proximity Weight") and the expected median transportation distance and combined waiting list and post-transplant deaths. As the efficiency weight (shown on the top of the figure) is decreased (moving to the right of the figure), the number of deaths (shown on the left) decreases and the median transportation (bottom) increases. The relationship is not linear; instead, the greatest impact on the number of deaths is seen among the higher proximity weights, and the greatest impact on median transportation distance is seen among lower proximity weights.

<sup>&</sup>lt;sup>40</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf

<sup>&</sup>lt;sup>41</sup> OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325\_lung\_meeting\_summary.pdf.

<sup>&</sup>lt;sup>42</sup> This analysis was conducted by Ted Papalexopoulos, Dimitris Bertsimas and Nikos Trichakis with the MIT Operations Research Center using the 2009-2011 TSAM cohort, with the acceptance model from 2015. It uses the LAS calculation approved at the 2020 OPTN Board of Directors and assumes waiting mortality and post-transplant outcomes are weighted evenly. CPRA and living donor priority are not included since that information was not included in the TSAM cohort.

<sup>&</sup>lt;sup>43</sup> OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325\_lung\_meeting\_summary.pdf.

Based on this analysis and the earlier scenario modeling, the Committee chose to focus on modeling the difference between 10%, 15% and 20% weights on efficiency.

The Committee also considered modeled transplant rates and mortality rates for pediatric candidates using different weights for pediatrics from the MIT optimization analysis. In *Figure 7*, each green dot represents the output of one simulation model run. The Committee used this analysis to narrow in on which weight for pediatric status guaranteed sufficient access for pediatric candidates. The goal was to ensure that pediatric candidates maintained at least as much access as they have in the current system, and that most pediatric candidates would have a high likelihood of transplant.

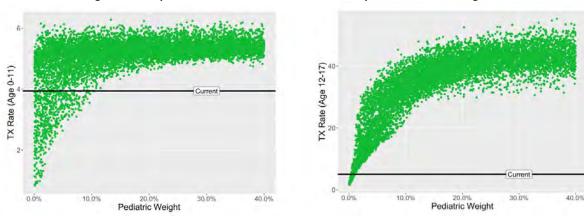


Figure 7: Transplant Rates for Children 0-11 and 12-17 by Pediatric Status Weight<sup>44</sup>

In **Figure 7**, the transplant rate for candidates under 18-years-old varies more and includes lower transplant rates when the weight placed on pediatric status is less than 10%. However, the transplant rate narrows into higher transplant rates when the pediatric weight is 10-20%, and there is not much difference in the transplant rates once the weight assigned pediatric candidates is above 20%.

The Committee chose a conservative approach and set a pediatric weight of 20% in consideration of the fact that the community placed access for pediatric candidates as one of the very highest priorities and in an attempt to avoid the risk of disadvantaging this population.<sup>45</sup>

There was no significant difference between the weights of 11% and 17% for candidate biology in the first round of modeling. MIT optimization analysis showed that weight over 10% risked overcompensating so that candidates with blood type AB and A would have a worse transplant rate than candidates with blood types O and B.<sup>46</sup> SRTR modeling confirmed that the most benefit in terms of equalizing the variation in transplant rates and waitlist deaths based on blood type could be gained around 5%.<sup>47</sup> Additionally, the analysis of the current system showed approximately 5% is placed on blood type. Therefore, the Committee chose to model only 15% for biological disadvantages (evenly split into 5% each for blood type, CPRA and height).

<sup>&</sup>lt;sup>44</sup> OPTN Lung Transplantation Committee, *Meeting Summary*, March 25, 2021. (Accessed June 14, 2021) https://optn.transplant.hrsa.gov/media/4567/20210325 lung meeting summary.pdf.

<sup>&</sup>lt;sup>45</sup> Continuous Distribution of Lungs Summer 2020 Prioritization Exercise, Community Results, October 15, 2020. (Accessed June 13, 2021) https://optn.transplant.hrsa.gov/media/4157/2020-10\_report\_community\_ahp\_prioritization.pdf.

 $<sup>^{\</sup>rm 46}$  OPTN Lung Transplantation Committee, Meeting Summary, March 31, 2021.

<sup>&</sup>lt;sup>47</sup> SRTR, Continuous Distribution Simulations for Lung Transplant, Data Request ID# LU2020\_05, February 12, 2021. https://optn.transplant.hrsa.gov/media/4450/lu2020\_05\_cont\_distn\_srtr\_1.pdf.

The Committee remained committed to providing some weight for prior living donors (who donated any organ), and placed an even 5% weight on this factor in the second round of SRTR modeling based on community feedback that it should be included. This is not included in the current lung allocation, so it would require a new data field.

The Committee chose to model three options for combined weight on waitlist survival and post-transplant outcomes as well - 40%, 45% and 50%, in line with the range of community responses to the AHP exercise.

The full list of weights modeled in the second round by both goal and attribute under each goal is listed in **Table 2** below.

Table 2: Modeled Weights by Goal and Attribute (TSAM Round 2) 48

| Goals                    |        | 1:1 LAS |        |        | 2:1 LAS |        |
|--------------------------|--------|---------|--------|--------|---------|--------|
| Attributes               | 10% PE | 15% PE  | 20% PE | 10% PE | 15% PE  | 20% PE |
| Waitlist survival        | 25%    | 22.5%   | 20%    | 33.3%  | 30%     | 26.3%  |
| Post-transplant outcomes | 25%    | 22.5%   | 20%    | 16.7%  | 15%     | 13.7%  |
| Biological Disadvantages | 15%    | 15%     | 15%    | 15%    | 15%     | 15%    |
| ABO                      | 5%     | 5%      | 5%     | 5%     | 5%      | 5%     |
| CPRA                     | 5%     | 5%      | 5%     | 5%     | 5%      | 5%     |
| Height                   | 5%     | 5%      | 5%     | 5%     | 5%      | 5%     |
| Patient Access           | 25%    | 25%     | 25%    | 25%    | 25%     | 25%    |
| Pediatric                | 20%    | 20%     | 20%    | 20%    | 20%     | 20%    |
| Prior living donor       | 5%     | 5%      | 5%     | 5%     | 5%      | 5%     |
| Efficiency               | 10%    | 15%     | 20%    | 10%    | 15%     | 20%    |
| Proximity Efficiency     | 5%     | 7.5%    | 10%    | 5%     | 7.5%    | 10%    |
| Travel Efficiency        | 5%     | 7.5%    | 10%    | 5%     | 7.5%    | 10%    |

As shown in **Table 3**, waiting list deaths decreased significantly, the proportion of organs expected to fly decreased, and the median travel distance increased, in all of the modeled scenarios.

<sup>&</sup>lt;sup>48</sup> Scenarios are identified by shortened titles. PE is the proximity efficiency score for the scenario and LAS represents the balance between waitlist survival and post-transplant outcomes points.



Table 3: Overall Outcomes by Scenario (Round 2)49

| Outcome  | Current | Efficiency<br>10%<br>LAS 1:1 | Efficiency<br>15%<br>LAS 1:1 | Efficiency<br>20%<br>LAS 1:1 | Efficiency<br>10%<br>LAS 2:1 | Efficiency<br>15%<br>LAS 2:1 | Efficiency<br>20%<br>LAS 2:1 |
|--|---------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| Transplant Rate<br>(per patient<br>year) <sup>50</sup> | 1.77    | 1.60                         | 1.63                         | 1.64                         | 1.59                         | 1.61                         | 1.62                         |
| Waitlist Mortality Count                               | 435     | 260                          | 269                          | 280                          | 231                          | 236                          | 247                          |
| Percent Died by 2<br>years Post-<br>transplant         | 23.38   | 23.44                        | 23.64                        | 24.08                        | 23.71                        | 24.07                        | 23.86                        |
| Median Donor-<br>Recipient Distance<br>(NM)            | 195     | 353                          | 283                          | 236                          | 345                          | 288                          | 245                          |
| Percent Expected to Fly (>75NM)                        | 81.32   | 79.02                        | 73.12                        | 69.42                        | 78.17                        | 73.53                        | 70.63                        |

The biggest single factor affecting waitlist mortality was waiting list survival weight. In fact, changes to waiting list survival weight had the greatest impact on candidate mortality overall because the changes to post-transplant outcomes did not change the percent of recipients who died in the first 2 years post-transplant very significantly.<sup>51</sup>

1,520
1,500
1,480
1,460
1,420
1,400

40%
45%
50%

Figure 8: Combined 1-Year Waiting List Survival and 2 Year Post-Transplant Survival<sup>52</sup>

<sup>&</sup>lt;sup>49</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf

Transplant rate is calculated by dividing the total transplants but the total waiting time of all candidates. The change in transplant rate is a result of an increase in waiting time for candidates who can wait longer for a transplant rather than a decrease in the number of transplants. SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf 

SRTR modeling used 2-year post transplant outcomes as a measure of the impact of the scenarios evaluated in the TSAM model. Although there was sufficient information in the data set used to recalculate the post-transplant outcomes for the LAS coefficients based on 5-year post-transplant outcomes, the data available was only sufficient to provide 2-year post-transplant outcomes to measure the differences in the TSAM runs.

<sup>&</sup>lt;sup>52</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf

As seen in **Figure 8**, the highest candidate survival (combined waiting list and post-transplant) among the SRTR round 2 models is expected when 50% of the weight is divided evenly between waiting list survival and post-transplant outcomes (25% each).

The Committee members discussed the limitations associated with calculating post-transplant outcomes based on the information currently available at the time of a match, since things like transplant procedure complications can play a role, and whether that should weigh in favor of placing more weight on waitlist survival. However, in order to provide the most utility, considering combined waiting list and post-transplant survival as shown in **Table 4**, and balancing the longevity of the graft, the Committee proposes weighing waiting list survival and post-transplant outcomes equally, giving each a weight of 25%.

#### Feedback Requested:

• Is the equal balance of waiting list survival weight and post transplant outcomes weight appropriate?

### **Rating Scales**

Within the total available points for each attribute, a candidate's specific points for that attribute are determined based on a rating scale. Each attribute uses a rating scale that ranges from 0-100. Candidates are assigned a score from 0-100 according to the rating scale specific to that attribute. Each attribute's rating scale score is then multiplied by the weight (0-100%) given for that attribute. These weighted scores are then aggregated to produce the candidate's composite allocation score.

For example, within the 25 points available for waiting list survival, a candidate could receive any portion of those points, based on their expected mortality within a year while awaiting transplant. A transplant candidate who is unlikely to survive one day without a transplant might receive the full 25 points, while a candidate who would be expected to live nearly a year without a transplant might receive only a fraction of a point for medical urgency. The rating scale determines exactly how many points a candidate would receive, out of the available points. The equation for the composite score is:

```
Score = (W_{MU} \times R_{MU} + W_{PTO} \times R_{PTO} + W_{ABO} \times R_{ABO} + W_{CPRA} \times R_{CPRA} + W_{HGT} \times R_{HGT} + W_{PED} \times R_{PED} + W_{PLD} \times R_{PLD} + W_{TE} \times R_{TE} + W_{PE} \times R_{PE})
```

In this equation, W represents the weight placed on the attribute and R represents the points for the candidate based on the rating scale for that attribute. For the subscripts:

MU = Medical Urgency

PTO = Post-Transplant Outcomes

ABO = ABO

CPRA = CPRA

HGT = Height

PED = Pediatric

PLD = Prior Living Donor

TE = Travel Efficiency

PE = Proximity Efficiency

So  $W_{MU}$  x  $R_{MU}$  would be the weight for medical urgency (25) times the particular candidate's expected waitlist survival score. For instance, if a candidate's waitlist survival score, based on the multiple factors that are used to predict waitlist survival, was 75.608, that would be multiplied by 25% (the waiting list urgency weight), and would result in 18.902 points for waitlist urgency. That 18.902 would be added to the points from the other attributes and result in that candidate's CAS.

Each attribute has a rating scale. The Committee chose the following rating scales:

- 1. Waitlist survival: A curve where y=points and x=WLAUC, based on the recent LAS update expected to be implemented in the third quarter of 2021.
- 2. Post-transplant outcomes: A linear relationship between points and the post-transplant area under the curve (PTAUC) based on changes to the PTAUC from what is currently in policy to include 5-year post-transplant outcomes.
- 3. Biological disadvantages: A steep non-linear curve for each of the three attributes. Each attribute is assigned a third of the weight given to "candidate biology" in the table.
  - a. Blood type
  - b. CPRA
  - c. Candidate height
- 4. Patient access: Binary for both attributes. Pediatric weight (20%) is greater than prior living donor weight (5%).
  - a. Pediatric: Points assigned to candidates aged 0-<18 years old at listing.
  - b. Prior living donor: Points assigned to candidates who previously donated any organ for transplant.
- 5. Proximity Efficiency: There are two components (travel efficiency and proximity efficiency), each of which gets half the weight given to "efficiency".
  - a. The proximity efficiency curve is a combination of a sigmoidal curve and a line segment, capturing the efficiencies of proximity other than cost.
  - b. The travel efficiency curve is a piecewise linear curve, with four segments between 0 and 100 miles and one segment from 100 to 6,000 miles.

#### **Waitlist Survival Scale**

The Committee proposes using the same measure of waitlist survival as the current system –Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list. It is currently one portion of the LAS, but will be considered separately under continuous distribution.

A candidate will receive waitlist survival points based on their expected number of days to live without transplant. Using the curved scale, the candidate would be assigned the most points if they are the least likely to be able to wait another day without receiving a transplant, with more points assigned for a 1-day difference when the candidate has only a few days expected to live if they do not receive a transplant than a 1-day difference when a candidate has nearly a year expected to live if they do not receive a transplant. In **Figure 10** below, you can see that the distance between waiting list urgency points is fewer days on the left, among the candidates with the least time left, and there are more days between score changes on the right, among candidates with longer life-expectancy while awaiting transplant.

This decision was based on the Committee's concern that the likelihood of another appropriate offer also decreases in a nonlinear fashion, and it is more appropriate to increase access more quickly as the

life expectancy decreases in order to preserve equity. In considering ethical principles, waitlist urgency is a measure of equity rather than utility.<sup>53</sup> If it were a utility measure, a linear scale would be appropriate (as with post-transplant outcomes below), because each day of life is equal from a utility perspective. However, as an equity measure, points are provided for waiting list urgency to help candidates receive a transplant before they are removed from the waiting list for death or because they are too sick to be transplanted. Using that analysis, each day is not the same. For a person that can wait 4 days, each day lost is a 25% reduction in their access. For a person that can wait 100 days, each day lost is a 1% reduction in their access.

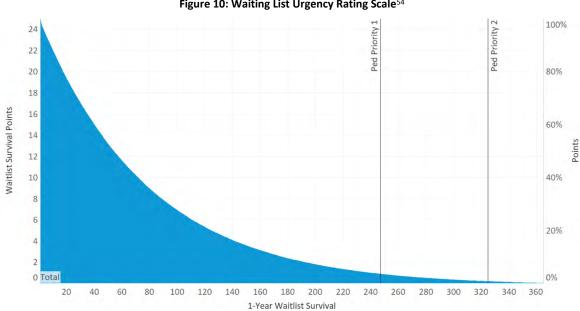


Figure 10: Waiting List Urgency Rating Scale<sup>54</sup>

As seen in Figure 10, candidates with the longest expected waiting list survival (shown in days on the bottom of the figure) receive the smallest percentage of the available waiting list survival points (shown on the right) which is the smallest waiting list survival points (shown on the left) out of the 25 possible points for waiting list survival. The percentage and therefore the number of points increases more steeply for candidates with the fewest days of expected waiting list survival.

#### Less than 12 years old

LAS is based on and used for candidates who are 12 years old or older. The current system uses two levels of priority for candidates who are less than 12 years old, priority 1 and priority 2.55 Priority 1 candidates are more medically urgent than priority 2 candidates. Since LAS and the priorities are used to express a candidate's wait list urgency, the Committee converted the priorities to the same scale used for candidates who currently have an LAS.

<sup>&</sup>lt;sup>53</sup> OPTN Ethical Principles in the Allocation of Human Organs, June 2015. Accessed June 27, 2021. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/.

<sup>&</sup>lt;sup>54</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

<sup>&</sup>lt;sup>55</sup> Based on age at time of match run.

The Committee proposes assigning candidates under the age of 12 a waitlist survival score based on the average survival of candidate in the same priority. As shown in **Figure 9**, Priority I candidates are estimated to have 247 days of survival without a transplant<sup>56</sup> and receive a waiting list survival score of 1.9075. Priority II candidates are estimated to have 325 days of survival without a transplant<sup>4</sup>, which translates to a waiting list survival score of 0.44. This will allow for candidates of all ages to use the same lung composite allocation score math and be ranked relative to one another, a significant advantage and step forward for lung allocation.

#### **Post-transplant Outcomes Scale**

Although the current LAS includes a measure of post-transplant outcomes, Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant, the Committee is proposing a change to that measure. The Committee proposes extending it to include the expected number of days a candidate will live during the first five years post-transplant. This will allow consideration of longer-term outcomes, and more stratification of candidates.

The Committee proposes a linear scale for post-transplant outcomes, since there is not an urgency that increases over time as there is with waitlist survival. This aligns with the ethical goal of utility, giving points to candidates based on how much use will be gained from the transplant, in terms of longevity of the graft. It also aligns with the requirement of the Final Rule that allocation policies be designed to achieve the best use of a donated organ.<sup>57</sup> The scale is below, in **Figure 11**, and shows that the points increase steadily through the 5 years.

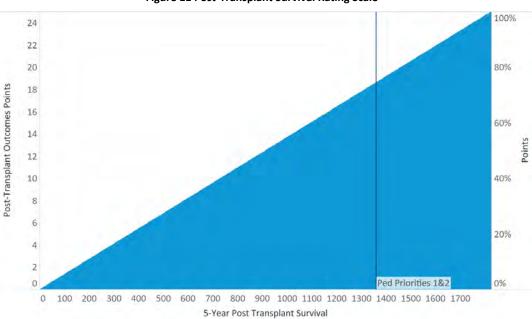


Figure 11 Post-Transplant Survival Rating Scale<sup>58</sup>

Candidates with the longest expected post-transplant survival would receive the full 25 possible points (100% of available points). As shown in Figure 11, as a candidate's expected post-transplant survival is

<sup>&</sup>lt;sup>56</sup> Based on SRTR analysis presented to the OPTN Lung Transplantation Committee during policy development.

<sup>&</sup>lt;sup>57</sup> 42 C.F.R. §121.8(a)(2).

<sup>58</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.



shorter, the candidate would receive a smaller percentage of the available points (as shown on the right of the figure), and therefore a smaller number of points (as seen on the left).

#### Less than 12 years old

The Committee proposes using the same scale for post-transplant outcomes for all candidates. In order to ensure that the score for candidates less than 12 (who do not currently receive an LAS) is appropriate, the Committee aligned the expected post-transplant for these candidates as a group on the same scale as the candidates who are at least 12.

For candidates less than 12 years old, the modeling used to determine PTAUC has historically been less reliable, as a result of the differences in these smaller pediatric patients as well as the very small samples sizes. Instead, lung uses a two-priority system for candidates under 12; priority 1 for the sickest candidates, and priority 2 for all others.

In order to calculate a composite allocation score for candidates less than 12 years old, the Committee needed to assign post-transplant outcomes scores to these candidates. Because the barriers to assigning a PTAUC are also barriers to post-transplant outcomes scores, the Committee considered assigning a fixed post-transplant outcomes score to all pediatric priority 1 candidates and a different fixed waiting list survival score for all pediatric priority 2 candidates, as is proposed for waiting list survival points for this group. However, when the Committee reviewed the modeling for 1 and 5-year post-transplant outcomes for candidates less than 12, the confidence intervals for the predicted 2 year post-transplant mortality of each priority overlapped, showing that there was not a significant difference in post-transplant outcomes between the two priorities.<sup>59</sup> In light of that information, the Committee proposes using the same score for all candidates less than 12, a score of 18.6325.

### **Candidate Biology Scales**

Candidate's access to transplant is affected by many different things, including biological differences between candidates, such as blood type, height, and sensitization. The OPTN has long addressed these inequities through allocation policies. These typically appear in the form of creating new classifications (such as by prioritizing candidates with blood types identical to the donor ahead of candidates with compatible blood types to the donor). The committee proposes a systematic approach whereby candidates are awarded points for their biological disadvantages according to a common scale. The clinical data drives how many points to award through a common calculation of that disadvantage.

The Committee proposes to align all three candidate biology ratings scales (ABO, CPRA and height) to a single curve, most clearly represented by the CPRA curve, because all three are measures of how hard it is for the candidate to match with a compatible donor, or incompatibility. For example, if a candidate could match with any donor based on that characteristic, 0 points would be awarded. Blood type AB candidates do not receive any ABO points, since they can accept any donor blood type. A candidate would receive the maximum points if there are very few donors that would be a match based on that characteristic, so, for example, candidates with a CPRA of 100% would get the most points for the CPRA factor. The scales are aligned so that candidates who only match with half of the donor pool (such as a candidate with either blood type O or CPRA of 50%) would get the same number of points.

<sup>&</sup>lt;sup>59</sup> SRTR *The impact of extending follow-up for the PTAUC model from 1 year to 5 years after transplant*, February 17, 2021. (Accessed June 18, 2021) https://optn.transplant.hrsa.gov/media/4675/lu\_posttx\_5y\_2\_2021.pdf.



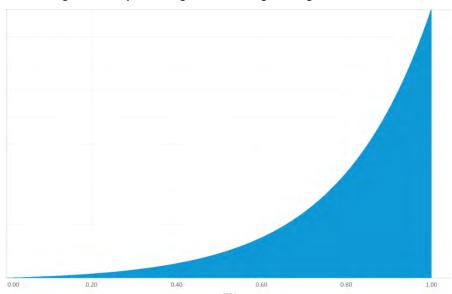


Figure 12. Shape of Biological Disadvantages Rating Scales<sup>60</sup>

The common curve is a steep curve that reflects a much larger difference in points awarded to candidates who are the hardest to match, and less of a difference among the candidates who are easier to match. The Committee also considered whether to adopt a linear scale, or a scale with a shallower curve. However, the Committee chose the steep curve because, much list waiting list survival, the difference in matching 1/100 and 2/100 impacts a candidate's likelihood of transplant more than the difference between matching 97/100 and 98/100 donors. The OPTN Histocompatibility Committee was supportive of this approach, which aligns with the current approach to CPRA in kidney allocation. The common curve all biological disadvantages scales are aligned to is shown in **Figure 12** above.

#### Blood Type (ABO) Rating Scale

The ABO rating scale is based upon the proportion of donors that are incompatible with a candidate based on the candidate's blood type. This proportion is then aligned with the overall candidate biology scale to come up with the ratings for blood type. Because even the hardest to match candidate blood type (O) is still able to accept approximately 50% of donors based on blood type, the blood type scale never awards the full points available under this attribute. The fact that the candidate biology scale is curved, with more distinction among the candidates who are hardest to match, results in less than 50% of the possible points being awarded for O candidates, as seen in **Figure 13** below. This is the result of the alignment across the candidate biology scales.

<sup>60</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.



Figure 13: ABO Rating Scale<sup>61</sup>

100%

80%

60%

2

40%

A

AB

B

O

#### Sensitization (CPRA) Rating Scale

Calculated panel reactive antibody (CPRA) values directly estimate the proportion of donors with which a HLA-sensitized candidate is HLA incompatible. CPRA is already in use in kidney allocation, and is a screening option for lung, but is not currently used in allocation sequencing for lung. <sup>62</sup> However, antibody sensitivity is a concern that affects the suitability of an organ for lung patients as well, and therefore limits the pool of appropriate donors for these lung candidates. <sup>63</sup> Therefore, the Committee decided to incorporate the CPRA attribute into the composite score. Although kidney allocation currently employs hard cutoffs of 98 or 99% CPRA, the Committee proposes incorporating CPRA in a more nuanced way, smoothing that hard boundary by using the steeply curved scale. <sup>64</sup>

 $<sup>^{61}\,</sup>https://public.tableau.com/profile/optn.committees \#!/vizhome/Continuous Distribution of Lungs/Home.$ 

<sup>&</sup>lt;sup>62</sup> OPTN Policies.

<sup>&</sup>lt;sup>63</sup> Y.D. Barac, M. Mulvihill, O. Jawitz, J. Haney, J. Klapper, M. Daneshmand, M. Hartwig, *High Calculated Panel Reactive Antigen* (cPRA) is Associated with Decreased Rates of Transplantation and Increased Waitlist Mortality in Lung Transplantation: A UNOS/OPTN Registry Analysis, The Journal of Heart and Lung Transplantation, Volume 38, Issue 4, S148.

<sup>&</sup>lt;sup>64</sup> Kransdorf EP, Pando MJ. Calculated panel reactive antibody with decimals: A refined metric of access to transplantation for highly sensitized candidates. Hum Immunol. 2017 Mar; 78(3):252-256. doi: 10.1016/j.humimm.2016.12.009. Epub 2017 Jan 6. Erratum in: Hum Immunol. 2017 Jul - Aug;78(7-8):522. PMID: 28069404.

The CPRA rating scale is depicted in **Figure 14** below.

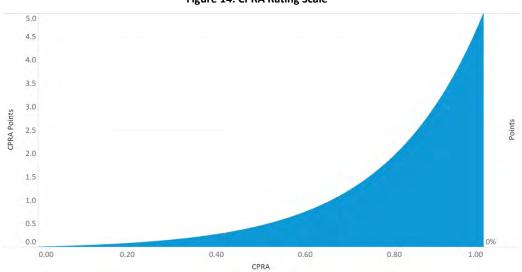


Figure 14: CPRA Rating Scale<sup>65</sup>

 $<sup>^{65}\,</sup>https://public.tableau.com/profile/optn.committees \#!/vizhome/Continuous Distribution of Lungs/Home.$ 



#### Height Rating Scale

The Committee also discussed other biological conditions that impact a candidate's access to transplant. In addition to blood type and CPRA, the Committee also proposes awarding points to candidates based upon their height.<sup>66</sup> Height is not currently used in lung allocation other than as a screening criteria that a transplant program can select, optionally, to exclude receiving offers from donors outside of the transplant program's height preferences for a particular candidate.

The height rating scale awards the highest points to the smallest and tallest candidates, as they have the most trouble finding an appropriate match.<sup>67</sup> The Committee proposed this new factor due to the known need for size matching, and difficulty finding an appropriately sized donor for candidates who are especially small or especially tall.<sup>68</sup>

The Committee proposes to use separate height scales by diagnosis because the size of the chest cavity is affected by the type of lung disease, whether it is obstructive, restrictive, or pulmonary arterial hypertension (PAH).<sup>69</sup> The proportion of incompatible donors was based on an analysis of the range of donor height accepted for candidates according to candidate height. This proportion of height incompatible donors was then combined with the candidate biology curve to create the rating scale for height.

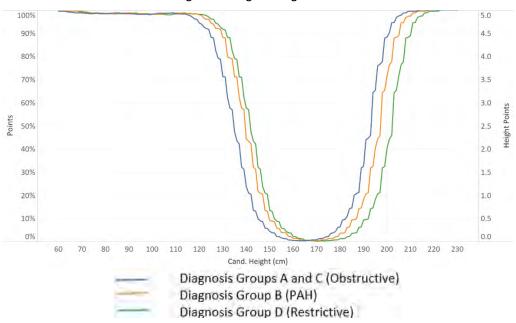


Figure 15: Height Rating Scales<sup>70</sup>

<sup>66</sup> The Committee also discussed size matching as a potential attribute related to post transplant outcomes. But due to community debates about the best way to measure lung cavity size, the Committee opted to address this in future iterations. Compare Reyes J. Perkins J, Kling C, Montenovo M. Size mismatch in deceased donor liver transplantation and its impart of graft survival. Clin Transplant. 2019; 00:e13662. https://doi.org/10.1111/ctr.13662 (DR\_BSAR, donor to recipient body surface area ratio); Ganapathi AM, Mulvihill MS, Englum BR, et al. Transplant size mismatch in restrictive lung disease. Transpl Int. 2017; 30(4):378-387. https://doi.org/10.1111/tri.12913 (pTLC, predicted total lung capacity); Eberlein M, Reed RM. Donor to recipient sizing in thoracic organ transplantation. World J Transplant. 2016; 6(1):155-64; Barnard JB, Davies O, Curry P, et al. Size matching in lung transplantation: an evidence-based review. J Heart Lung Transplant. 2013; 32(9):849-60. https://doi.org/10.1016/j.healun.2013.07.002.)

<sup>&</sup>lt;sup>67</sup> OPTN Lung Transplantation Committee, Continuous Distribution Data Workgroup, Meeting Summary, August 12, 2020.



#### **Candidate Access Scales**

#### Age

The Committee proposes a binary rating scale to assign points for pediatric access. Candidates who are under the age of 18 at the time they are registered on the waiting list will receive the full benefit of the pediatric points, and candidates who are over the age of 18 will receive none. This is consistent with the OPTN determination that it is ethically appropriate to provide some preference to pediatric candidates. The OPTN Ethical Principles of Pediatric Organ Allocation cite Norman Daniel's Prudential Lifespan Account the Fair Innings Principles, and John Rawl's Maximin Principles to justify pediatric prioritization. The principles also justify the priority using utility considerations ("[A]cross the entire population of pediatric versus adult transplant recipients, pediatric transplant recipients will on average enjoy lower mortality rates due to the strong association between younger age and longer survival.") In other words, these ethical principles support the Committee's determination that prioritizing pediatric candidates is the best use of donated organs. Additionally, these justifications used in the OPTN Ethical Principles of Pediatric Organ Allocation also meet the requirement of the National Organ Transplant Act (NOTA) to "recognize the differences in health and in organ transplantation issues between children [under the age of 18] and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children."

This is a shift from the current lung policy, which groups candidates into three age groups, under 12, 12-17 (adolescent) and 18 and over (adult). It is also consistent with the advice from the Pediatric Transplantation Committee to adopt a consistent approach for all organs as they transition to continuous distribution.

For pediatric points assignment, the Committee proposes that candidates either receive all of the points for pediatric or none, and is not proposing a sliding scale system where a candidate might get more points for being the youngest candidate than for being 17 years old, for example. The primary reason for using a sliding scale would have been to account for the additional difficulties in matching candidates who are especially small, but the Committee was able to include points for height that are awarded in

<sup>&</sup>lt;sup>68</sup> Keeshan BC, Rossano JW, Beck N, Hammond R, Kreindler J, Spray TL, Fuller S, Goldfarb S., Lung transplant waitlist mortality: height as a predictor of poor outcomes, Pediatr Transplant. 2015 May; 19(3):294-300. doi: 10.1111/petr.12390. Epub 2014 Nov 19. PMID: 25406495. Sell JL, Bacchetta M, Goldfarb SB, Park H, Heffernan PV, Robbins HA, Shah L, Raza K, D'Ovidio F, Sonett JR, Arcasoy SM, Lederer DJ. Short Stature and Access to Lung Transplantation in the United States. A Cohort Study. Am J Respir Crit Care Med. 2016 Mar 15; 193(6):681-8. doi: 10.1164/rccm.201507-1279OC. PMID: 26554631; PMCID: PMC5440846. Weill D. Access to Lung Transplantation. The Long and Short of It. Am J Respir Crit Care Med. 2016 Mar 15; 193(6):605-6. doi: 10.1164/rccm.201511-2257ED. PMID: 26977969.

<sup>••</sup> IDIU.

 $<sup>^{70}\,\</sup>underline{https://public.tableau.com/profile/optn.committees\#!/vizhome/ContinuousDistributionofLungs/Home.}$ 

<sup>&</sup>lt;sup>71</sup> OPTN Ethical Principles of Pediatric Organ Allocation, November 2014. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation.

<sup>&</sup>lt;sup>72</sup> Daniels, N. Just Health: Meeting Health Needs Fairly. New York: Cambridge University Press, 2008.

<sup>&</sup>lt;sup>73</sup> Williams, A., "Intergenerational Equity: An Exploration of the 'Fair Innings' Argument." Health Economics 6 (1997): 117-32.

<sup>&</sup>lt;sup>74</sup> Rawls, J. A Theory of Justice. Cambridge: Belknap Press, 1971.

<sup>&</sup>lt;sup>75</sup> OPTN Ethical Principles of Pediatric Organ Allocation.

<sup>&</sup>lt;sup>76</sup> OPTN Ethical Principles of Pediatric Organ Allocation.

<sup>&</sup>lt;sup>77</sup> 42 USC § 274(b)(2)(M).

proportion to the difficulties in finding a match. The use of the height scale is able to more directly address the specific factor, and align the points with the specific disadvantage.<sup>78</sup>

#### **Prior Living Donors**

The Committee proposes points for prior living donors. Candidates who have previously donated any organ would receive the full benefit of the five prior living donor points, and candidates who have not donated would not receive any prior living donor points.

This concept exists in kidney allocation policy now and the Committee proposes to extend this benefit to lung allocation. There are both ethical and legal justifications for providing this priority to prior living donors. The ethical reasons include the ethical principle of making one whole as well as the physician's maxim to protect patients. For these reasons, the Ethics Committee supported prior living donor priority for any organ needed. However, the OPTN must develop organ allocation policies consistent with our legal obligations. NOTA requires that the OPTN create allocation policies in accordance with established medical criteria, while the OPTN Final Rule requires, amongst other requirements, that allocation policies be based on sound medical judgment, seek to achieve the best use of donated organs, and promote patient access to transplantation. In developing this specific aspect of the proposal, the Committee sought to keep all of these requirements in consideration and sought the advice of the Ethics Committee, and Living Donor Committee.

First, the threshold question is whether being a living donor is a medical criterion in the same sense as respiratory failure. The answer is clearly yes; all of these individuals were medical patients that underwent a surgical procedure at a hospital. This distinguishes non-medical criteria such as donating money to transplant research, having a family member be a deceased donor, signing up to be a deceased donor, etc. which are excluded from organ allocation policy. As such, being a prior living donor is a criterion that the OPTN can consider when developing allocation criteria, while continuing to appropriately exclude rewarding those who donate in non-medical ways to the transplant system.

"Sound medical judgment" is not defined by NOTA or the OPTN Final Rule. It "is an ambiguous term that is synonymous with the term 'decision-making.' It results from critical thinking and clinical reasoning." One manner in which this manifests is through consensus following thoughtful discussion among informed medical professionals. They would need to be informed of the risks, benefits, and tradeoffs regarding their decision. As it relates to prioritizing prior living donors, the Board and multiple committees have discussed this concept over the years and all of them have agreed that prior living donors should receive some priority. 85

<sup>&</sup>lt;sup>78</sup> OPTN Lung Transplantation Committee, Continuous Distribution Data Workgroup, Meeting Summary, August 12, 2020.

<sup>&</sup>lt;sup>79</sup> OPTN Ethics Committee Meeting Summary, March 11, 2021.

<sup>80 42</sup> U.S.C. §274(b)(2)(A)(ii)

<sup>81 42</sup> C.F.R. §121.8(a)(1)

<sup>82 42</sup> C.F.R. §121.8(a)(2)

<sup>83 42</sup> C.F.R. §121.8(a)(5)

<sup>&</sup>lt;sup>84</sup> Manetti, Wendy. "Sound Clinical Judgment in Nursing: A Concept Analysis." Nursing Forum 54, no. 1 (January 2019): 102–10. https://doi.org/10.1111/nuf.12303.

<sup>&</sup>lt;sup>85</sup> OPTN, Kidney Committee Report to Board, Dec 13, 2006. OPTN, Minutes from Meeting of Ethics Committee, April 2, 2012. Letter from Liver Committee to Living Donor Committee, Feb 23, 2015.

The "best use of donated organs" is an ambiguous term and can be candidate specific or system wide. Prior living donors provide a benefit to the entire system. Each year, there are roughly 500 living donors and maybe 40 prior living donors added to the waiting list. 86 Across the system, this brings a benefit to the transplant system. Anecdotally, several transplant professionals stated that the prior living donor priority is an important part when discussing living donation with potential prior living donors.

Similar to the best use requirement in the Final Rule, the regulation also requires the OPTN to promote patient access to transplantation.<sup>87</sup> While this priority clearly promotes access for prior living donors, it also promotes access for other candidates. As mentioned above, there are more living donor organs transplanted each year than prior living donors added to the waiting list. This has a net effect of lowering the number of candidates waiting for a transplant – or increasing access to transplant for those candidates that do not receive a living donor organ.

#### **Promoting the Efficient Management of the Organ Placement System Scales**

Although the Committee chose to use distance as the measure of placement efficiency, the amount of travel is not the goal of the Committee's use of distance; rather, as illustrated in **Error! Reference source not found.5**, travel has an impact on organ placement efficiency. Generally speaking, the following statements are true: travel distance impacts travel time; the farther an organ is transported, the more likely it is to travel by air than ground; and air travel is more expensive than ground travel for the same distance; <sup>88</sup> Finally, financial costs are only one aspect of overall system efficiency.

The Committee started with a focus on how to determine the mode of travel. The Committee reviewed information from the UNOS Organ Center, a recent Operations and Safety survey, and published literature regarding travel modes for organ transportation. <sup>89</sup> The Committee also solicited information from AOPO members, the SRTR, and other workgroup members about how to determine the mode of travel.

The Committee discussed several attributes that could influence the travel mode: distance between the donor and transplant hospital; travel time; time of day; donor organ characteristics; urbanicity; flight availability; etc. Some of these cannot be known at the time of organ offer and therefore could not be used to prioritize organ offers. (For example, time of procurement is not known before the organ is offered.) The Committee also discussed how granularly to predict travel mode or costs. There exists a spectrum of options available. These options can be considered along a range from the least precise estimate of impact to system efficiency to the most precise estimates (**Figure 16**). This range also coincides with options that are the most transparent to the least transparent. In other words, options that are more precise typically rely upon live or proprietary information and would likely be less transparent to the community while options that are less precise typically rely upon easily obtainable information and are more transparent.

<sup>&</sup>lt;sup>86</sup> J. Wainright, D. Klassen, A. Kucheryavaya, and D. Stewart, Delays in Prior Living Kidney Donors Receiving Priority on the Transplant Waiting List. Clinical journal of the American Society of Nephrology: CJASN, 11(11), 2047–2052 (2016). https://doi.org/10.2215/CJN.01360216.

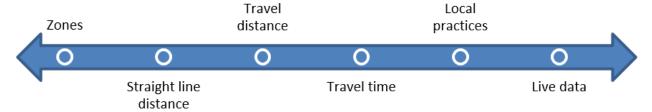
<sup>87 42</sup> C.F.R. §121.8(b)(2).

<sup>&</sup>lt;sup>88</sup> S. Gentry, E. Chow, N. Dzebisashvili, et al. The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients. Am J Transplant. 2016; 16(2):583-93. Dubay DA, Maclennan PA, Reed RD, et al. The impact of proposed changes in liver allocation policy on cold ischemia times and organ transportation costs. Am J Transplant. 2015; 15(2):541-6.

<sup>&</sup>lt;sup>89</sup> OPTN Operations and Safety Committee, Transportation Report (2018), available at: https://optn.transplant.hrsa.gov/media/2766/liver\_boardreport\_201812.pdf.



**Figure 16: Options for Determining Travel Costs** 



The Committee chose to use straight-line distances to calculate relative travel costs based on a desire to be as transparent as possible, especially as part of this large allocation change. However, the Committee did consider this an area where it may be desirable to move to more specific measures in the future.

The scales for proximity efficiency and travel efficiency have multiple inflection points, based on certain changes to the way organs and procurement teams travel. Within 45 nautical miles (NM), lung procurement teams and procured lungs are more likely to travel via ground transportation. Within the zone of 45-90 NM, the likelihood of travel by air is increasing, and over 90 NM, most travel for lung recovery is by private air transportation. The final inflection point is around 3,000 NM, beyond which most lung programs have their screening criteria set to exclude offers, as shown in **Figure 17**.

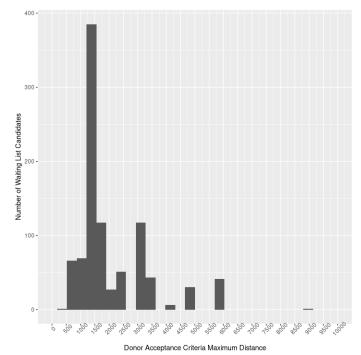


Figure 17: Donor Acceptance Criteria for Maximum Distance by Number of Lung Candidates 91

round-down, or truncate, distances to the integer level.

<sup>&</sup>lt;sup>90</sup> OPTN Ethical Principles in the Allocation of Human Organs, 2015. <a href="https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/">https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/</a>. The OPTN will use the Haversine method to calculate these distances between the latitude and longitude of the donor and transplant hospitals. Due to differences in calculating these locations, the OPTN will

<sup>91</sup> OPTN data as of November 2020.



The distance at which lungs are more likely to use air transportation than ground transportation is similar to livers but different from the distances where this change takes place for kidney recovery. Because cold ischemic time does not have a significant negative impact on kidneys as soon as it does on lungs, kidney transportation patterns are different from the patterns seen with livers, heart, and lungs. Livers, hearts, and lungs are more likely to use private air than kidneys, which are more often transported on commercial flights. Therefore, the Committee chose to anchor to literature on travel methods for livers<sup>92</sup> rather than travel analysis conducted on kidneys.

The shape of these placement efficiency scales allows for smarter distribution of lungs. Instead of treating all lung offers within 250 NM the same, there is additional weight placed on those that are closest. Modeling suggests more organ transplants within the first 50 NM, a larger average distance for organs, but then less organs travelling by air. This achieves the goal of smarter distribution: shipping organs only for significant clinical differences. While the number of lungs placed within 50NM increases, flying is reduced, even though median travel distances increased. **Figure 18** shows the distribution of transplants by distance from the donor hospital in the proposed system compared to the current system.

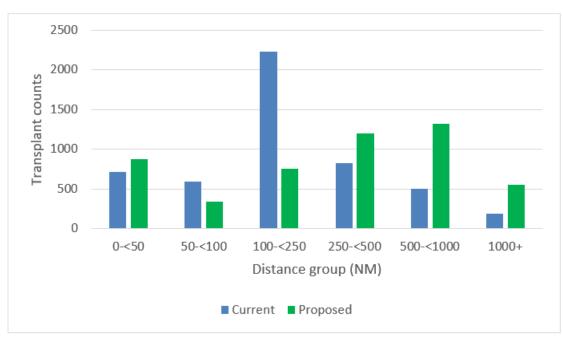


Figure 18: Transplant Counts by Distance Comparison to Current<sup>93</sup>

In fact, the modeling shows that in the current system, most of the travel is for the candidates with the lowest LAS. That means that transplant hospitals are traveling farthest for the least urgent candidates and traveling the least for the most urgent candidates. In the proposed system, this is largely reversed.

<sup>&</sup>lt;sup>92</sup> Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL. The impact of redistricting proposals on health care expenditures for liver transplant candidates and recipients. American Journal of Transplantation. 2016 Feb; 16(2):583-93.

<sup>&</sup>lt;sup>93</sup> SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf.

As seen in *Figure 19*, SRTR modeling shows that the highest LAS candidates (who need the lung the most urgently) will be able to accept offers from farther away, and transplant hospitals will be less likely to travel farther for the candidates who have lower LAS and may be able to wait for a closer offer.<sup>94</sup>

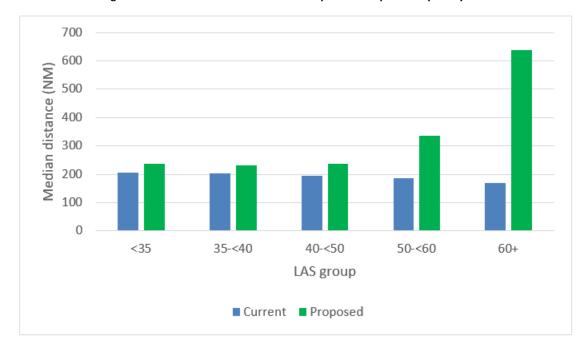


Figure 19: Median Distance from Donor Hospital to Recipient Hospital by LAS

<sup>&</sup>lt;sup>94</sup> Note: The modelling shows that organs offered long distances will more frequently be offered to high LAS candidates. This does not mean that high LAS candidates will only receive offers from far away or with high cold ischemic time.



#### Travel Efficiency Rating Scale

Travel efficiency is the measure of the efficiency of traveling shorter distances and the associated reduction in travel costs. Since a direct measure of these costs is not available, the Committee chose approximate inflection points. The proposed scale for travel efficiency gradually decreases from 0-45NM, reflecting small differences in costs associated with driving greater distances. Then the rating scale declines more sharply between 45 and 90 nautical miles, since air travel may be required in this range, based on polling clinicians and published literature on transportation of livers for transplantation. Beyond about 90 nautical miles, it is estimated that lungs will nearly always be transported by air. Once traveling by air, the added cost of traveling further distances is incremental, as reflected in the relatively shallow, but steady rating scale slope.

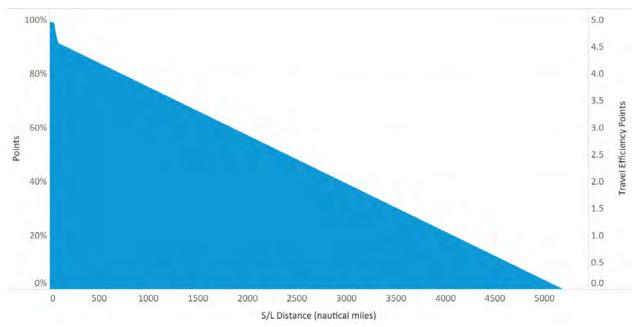


Figure 20. Travel Efficiency Rating Scale<sup>96</sup>

<sup>&</sup>lt;sup>95</sup> OPTN Thoracic Committee Continuous Distribution of Lungs Workgroup Meeting Minutes, May 16, 2019. https://optn.transplant.hrsa.gov/media/3086/20190516\_lungworkgroup\_summary.pdf. Gentry SE, Chow EK, Dzebisashvili N, Schnitzler MA, Lentine KL, Wickliffe CE, Shteyn E, Pyke J, Israni A, Kasiske B, Segev DL. The impact of redistricting proposals on health care expenditures for liver transplant candidates and recipients. American Journal of Transplantation. 2016 Feb; 16(2):583-93.

<sup>96</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.



The changes within the first 300 NM to adjust for the changes in travel methods are shown more closely in **Figure 21** below.

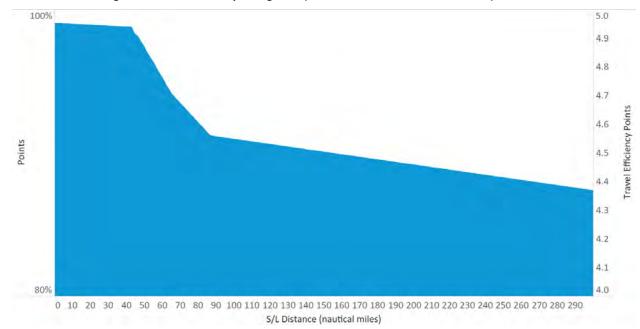


Figure 21. Travel Efficiency Rating Scale (Zoomed in to 0 to 300 Nautical Miles)<sup>97</sup>

#### **Proximity Efficiency Rating Scale**

The proximity efficiency rating scale is a measure of the efficiency of transporting lungs shorter distances other than decreased transportation costs. These include differences such as the time in transit for transplant teams, additional effort required to coordinate longer travel, and differences in the chance of something going wrong in transit the farther the personnel and lungs must travel.

The rating scale for proximity efficiency provides the most points for candidates who are listed closest to the donor hospital. Rather than providing a steady difference in points as distance changes, the rating scale for proximity points provides the maximum points for any distance within 45NM, within which almost all travel would be expected to be by ground transportation. There is a steep decrease in points from 45-90NM where there would be some air travel and some ground travel.

For distances beyond 90NM, the rating scale follows a sigmoidal mathematical function (S-curve). This curve is gradual at first, accounting for little significant difference in the efficiency of a short flight compared to a slightly longer flight. The curve drops more steeply again after 3,000NM, the distance beyond which lung transplants are very rarely performed. <sup>98</sup>

<sup>97</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

<sup>&</sup>lt;sup>98</sup> OPTN Lung Committee Meeting Minutes, Nov. 12, 2020.



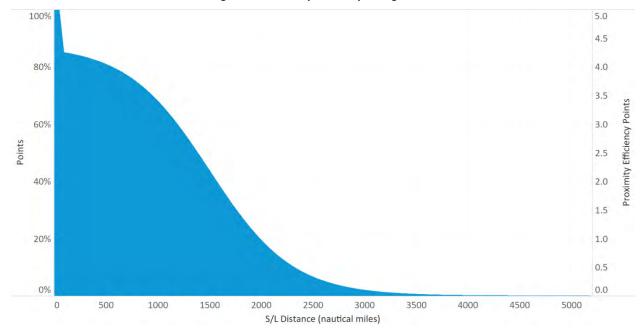


Figure 22: Proximity Efficiency Rating Scale<sup>99</sup>

There are times when a lung is imported from outside the United States of America and transplanted into a candidate inside the US.<sup>100</sup> In these instances, distance will be calculated based on the location of the US donor hospital closest to the recovery hospital outside of the US.

### **Other Considerations**

Due to the structural changes inherent in converting from a classification-based system to a points-based system, the Committee is also proposing necessary changes to the other areas of policy. These include the clinical values update schedule, waiting time, multi-organ allocation, and exceptions.

### **Update Schedule**

Given the new scoring system, the Committee considered what candidate clinical values would need to be updated, and on what frequency. The Committee proposes fundamentally shifting away from the concept of LAS and to the new system of scores for specific goals and attributes, and an overall CAS. In that system, the Committee does not want to continue anchoring choices to what the LAS would be. Therefore, the Committee proposes removing the current requirement for more frequent reporting (every 14 days) when a candidate's LAS is 50 or higher.

After considering several options, including setting a waiting list survival score, the Committee proposes keeping the updates for most clinical values set at once every six-month period. It also proposes listing the values that require a right heart catheterization and continuing to allow transplant hospitals to wait

<sup>99</sup> https://public.tableau.com/profile/optn.committees#!/vizhome/ContinuousDistributionofLungs/Home.

<sup>&</sup>lt;sup>100</sup> Placement by the OPTN was attempted for lungs from one Canadian donor in the first quarter of 2021, and for lungs from six donors in the first quarter of 2020. OPTN data accessed July 1, 2021.

to update these only when they are being taken. Further, the policy is restructured so that it specifically lists the values that must be updated every 28-days, every six-months, or whenever they are changed.<sup>101</sup>

The Committee proposes a new requirement for more frequent updates. The current policy requires certain values to be updated every 14 days once a candidate's LAS is 50 or higher. <sup>102</sup> In the proposed policy, when a candidate is on an extracorporeal membrane oxygenation (ECMO) device, continuous ventilation, or high flow oxygen device, then the proposal would require that the transplant program update assisted ventilation and supplemental oxygen fields every 28 days. The Committee discussed ways to identify candidates who are likely to be the most medically urgent and so identify those most likely to receive a high CAS based on clinical values. High oxygen requirements were identified as the primary driver of candidate medical urgency which the Committee said is consistent with candidates dependent on ECMO, continuous ventilation, or high flow oxygen devices.

The Committee chose the 28-day update schedule based on a desire to balance administrative burden on the transplant hospital with the need to ensure that candidates are not unfairly advantaged if their condition improves. The Committee's experience has been that most candidates who are severely ill enough to fall into this category are unlikely to have their condition improve before they receive a transplant.

This will require updates to programming to collect ECMO and type of assisted ventilation on the waiting list, and not just when the candidate is removed from the waiting list. The Data Advisory Committee supported the inclusion of the new fields to better collect respiratory status of lung candidates.

### **Waiting Time**

Waiting time is used as a tiebreaker in current lung allocation. <sup>103</sup> Because LAS is calculated to 16 decimal places, it is rare that waiting time is ever needed to break a tie LAS; however, waiting time is sometimes used to break ties between candidates with exceptions. <sup>104</sup> Waiting time is used to further the ethical principle of justice related to medical need. <sup>105</sup> In the current system, waiting time is based only on active time for adults, and includes both active and inactive time for pediatric candidates. The Committee proposes adjusting waiting time so that it is awarded for all time on the lung waiting list, whether active or inactive, regardless of candidate age, and using waiting time as the only tie-breaker.

The Committee discussed this approach with the leaders of the other organ committees, who supported it as an approach that would work well across all organs as they transition to continuous distribution. It would create a single tie-breaker that would always be unique since it would be anchored to the candidate's registration time stamp, which is recorded in order with unique time stamps. Although the Committee believed that the ideal measure would be the person whose disease began first, total waiting time was an acceptable available measure for those rare instances when a tie between candidates would need to be decided.

<sup>&</sup>lt;sup>101</sup> OPTN Lung Committee Meeting Minutes, June 17, 2021.

<sup>&</sup>lt;sup>102</sup> OPTN Policy 10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher.

<sup>&</sup>lt;sup>103</sup> OPTN Policy 10.4.A Sorting Within Each Classification.

<sup>&</sup>lt;sup>104</sup> Between 2006 and 2020, there were only four matches with ties, and those were between multiple listings for the same candidate. OPTN data as of November 6, 2020.

<sup>&</sup>lt;sup>105</sup> Veatch & Ross, Transplantation Ethics, p. 302. For additional discussion of how ethical principals were integral to the development of this proposal, *see* OPTN Request for Feedback, Update on the Continuous Distribution of Organs Project, OPTN Lung Transplantation Committee. Public Comment Period August 4, 2020-October 1, 2020.



### Multi-Organ Allocation

Current policy uses the classifications, distance cut-offs, and LAS cut-offs in the circles allocation system to delineate when to offer lungs to multi-organ candidates relative to single organ candidates. This proposal addresses that by proposing maintenance of similar rules surrounding multi-organ allocation during the transition period of having lung allocation in a continuous distribution system and other organs not yet using continuous distribution. The plan is for the newly formed OPTN *ad hoc* Multi-Organ Transplantation Committee to address longer-term improvements to the multi-organ allocation system.

The Committee considered the distribution of heart-lung, lung-kidney, and lung-liver transplant recipients by what their CAS would be. The Committee chose to set a threshold of a CAS of 28 to include most multi-organ lung candidates while preserving access for single organ heart, kidney and liver candidates. The CAS cutoff (above which candidates are offered the second organ) will allow for a clean cutoff point on the match for OPOs.

The workgroup reviewed data on the statuses of multi-organ candidates who received heart-liver, lung-liver, heart-kidney, or lung-kidney transplants in 2019. Figure 23 shows the recipient statuses for these combinations of multi-organ transplants.

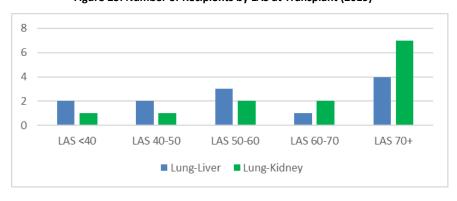


Figure 23: Number of Recipients by LAS at Transplant (2019)<sup>107</sup>

The OPTN Board of Directors approved changes to the allocation of lung-liver and lung-kidney combinations on June 14, 2021, which included offering livers and kidneys to lung candidates with a lung allocation score of greater than 35 or candidates less than 12 years old. The statuses were determined using the data shown above in **Figure 23.** For multi-organ transplants performed in 2019, the following multi-organ transplants would meet the recently approved criteria:

- Lung-liver 12 of 12
- Lung-kidney 13 of 13

 $<sup>^{106}</sup>$  Multi-Organ Policy Workgroup Meeting Summary, May 29, 2020. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/.

<sup>&</sup>lt;sup>107</sup> Ibid.

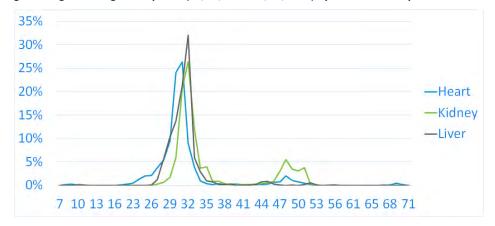
<sup>&</sup>lt;sup>108</sup> Notice of OPTN Policy Change, Clarify Multi-Organ Allocation Policy, Board Approved June 14, 2021. (Accessed June 28, 2021) https://optn.transplant.hrsa.gov/media/4698/clarify\_multi-organ\_june\_2021\_policy\_notice.pdf.

<sup>&</sup>lt;sup>109</sup> OPTN Public Comment Proposal, Clarify Multi-Organ Allocation Policy, January 21, 2021 – March 23, 2021. (Accessed June 28, 2021) <a href="https://optn.transplant.hrsa.gov/media/4354/2021">https://optn.transplant.hrsa.gov/media/4354/2021</a> pc opo clarify multi organ allocation policy.pdf.

The Committee wanted to balance access for single and multi-organ candidates similarly, and considered the distribution of lung-kidney, lung-liver, and heart-liver candidates by their estimated lung composite allocation score.

**Figure 24** shows the projected distribution of composite allocation scores for lung candidates that need a second organ.

Figure 24: Percentage of Lung Multi-Organ Recipients (01/01/2011-05/13/2021) by Estimated Composite Allocation Score<sup>110</sup>

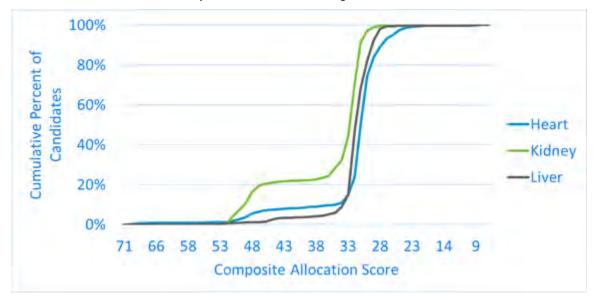


These were produced using lung matches performed in 2011 and afterwards, that resulted in lung transplants simultaneously with kidney, liver, or heart. The data is grouped by the second organ needed. For each of the organs, there is a bimodal distribution. The first and larger distribution occurs for adult candidates around a composite allocation score of 32-36. The second and smaller distribution occurs for pediatric candidates around 50.

**Figure 25** shows the cumulative percent of candidates that would be captured were the multi-organ cutoff set at a specified composite allocation score. Notice the large inflection in the curve in the area of 23-33.

<sup>&</sup>lt;sup>110</sup> OPTN Data as of June 11, 2021.

Figure 25: Lung Multi-Organ Recipients (01/01/2011-05/13/2021) by Percentage of Recipients with a Specific Estimated Composite Allocation Score or Higher<sup>111</sup>



**Table 4** is another look at the data displayed in the previous chart. The committee sought to capture 99% of the lung-kidney candidates and therefore chose 28 as the cutoff for the composite allocation score.

Table 4: Percentages of Lung Multi-Organ Recipients by Estimated Composite Allocation Score 01/01/2011-05/13/2021<sup>112</sup>

| <b>Composite Allocation Score</b> | Heart  | Kidney | Liver  | Total  |
|-----------------------------------|--------|--------|--------|--------|
| 32                                | 23.84% | 70.59% | 46.94% | 39.60% |
| 31                                | 50.19% | 91.27% | 68.23% | 62.93% |
| 30                                | 74.28% | 97.21% | 82.02% | 80.24% |
| 29                                | 83.76% | 98.96% | 92.39% | 89.44% |
| 28                                | 89.19% | 99.62% | 98.09% | 94.55% |
| 27                                | 93.02% | 99.88% | 99.36% | 96.79% |
| 26                                | 95.15% | 99.88% | 99.47% | 97.72% |
| 25                                | 97.24% | 99.91% | 99.52% | 98.61% |
| 24                                | 98.59% | 99.91% | 99.52% | 99.17% |
| 23                                | 99.13% | 99.91% | 99.52% | 99.40% |
| 22                                | 99.41% | 99.91% | 99.52% | 99.51% |

The Lung Committee suggests a slightly more conservative cut-off that would include 94.55% of the heart-lung, lung-liver and lung-kidney recipients. This threshold of a CAS of 28 will be used as a replacement for the threshold of LAS 35 in lung-kidney and lung-liver allocation. This is in line with the recently approved changes to lung-liver and lung-kidney, which create that cutoff of LAS of 25 based on similar data, showing all of these candidates who were transplanted in 2019 had an LAS of 35 or higher. However, this is a specific area where the Committee is requesting feedback from the community on whether the proposed cutoff is appropriate or would be more appropriately placed higher or lower.

 $<sup>^{\</sup>rm 111}$  OPTN Data as of June 11, 2021.

<sup>&</sup>lt;sup>112</sup> OPTN Data as of June 11, 2021.

For heart-lung combinations, the Committee proposes continuing to offer to high status heart candidates within 500 NM first. The Committee then proposes requiring that lungs and heart-lungs be offered off of the lung match run to candidates with a composite allocation score of at least 28 before a heart alone would be offered from the heart match run to candidates further than 500 NM from the donor hospital or listed at status 3 or lower. This would be a cleaner cut-off than the current system, not permitting heart alone allocation to continue until the heart was offered to all heart-lung candidates with a CAS of at least 28. Fundamentally, the Committee sought to balance the difficulty in finding an appropriate match for a candidate who requires multiple organs with the desire to provide earlier access to transplant for heart-alone candidates who are the sickest, according to their status, and with saving the largest number of lives possible with the limited supply of organs for transplant. Leadership of the Heart Transplantation Committee supported this approach.

The Committee also considered requiring that the heart be offered to every candidate who needed one on the lung match run before returning to the heart match run, but chose to include the cutoff of 28 to align with the lung-kidney and lung-liver cutoffs. This is an area where the Committee would especially like feedback regarding whether the cutoffs are appropriate and necessary.

#### Feedback Requested:

- Should offering hearts to heart-lung candidates off the lung match be required?
- If so, should there be a cutoff at a particular CAS?
- If so, what score makes sense, and why?

### **Exceptions**

The Committee proposes certain changes to the exception process. These changes will adjust to allow for exceptions to the new scoring system, and are also coordinated to allow for increased consistency between organs and to prioritize the most beneficial changes related to the costs of implementing a new system.

The existing lung review board is already structured appropriately to adjudicate lung exception requests, and no changes are proposed to the composition of the review board. However, certain changes to the types of exceptions that may be requested, and the specifics of review are proposed.

All of the current exception types (pediatric status 1, adolescent, LAS, diagnosis, and estimated value) would all end with the implementation of continuous distribution. In their place, this proposal would create exceptions based on each goal (waiting list survival, post-transplant outcomes, candidate biology, candidate access, and placement efficiency). A program would be able to request up to the maximum score within a given goal as an exception. No candidates would be able to get a composite allocation score above 100, with or without an exception. For those candidates with existing exceptions when these changes take effect, the Committee proposes converting those exceptions to waiting list survival and post-transplant outcomes score exceptions in order to allow the transplant programs and the review board time to transition reviews into the new paradigm.

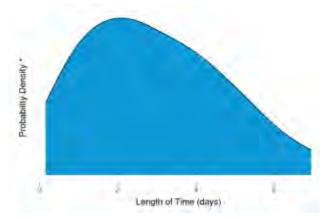
The Committee also proposes allowing a candidate to maintain an exception indefinitely once granted, rather than requiring renewal of exceptions after a certain period of time. Based on the clinical

experience of the Committee members and their experiences as lung review board members in the past, the Committee members noted that the situations in which exceptions are typically granted are circumstances either that do not improve, or that result in lasting impacts on the candidate's expected survival.

The Committee proposes reviewing all exceptions and appeals prospectively and removing the option to override (that is, to list a candidate at the exception status after the exception is denied, while the decision is under appeal). The override has not been used since DSAs were removed from lung allocation in 2017, and was only used 11 times between 2005 and 2017. Sixty lung exception denials have been appealed since 2005, and of those slightly more than 1/3 (24) were granted on appeal. There is no record of any lung exception cases being appealed to the lung committee. Therefore, even though the committee appeal option remains available, it is highly unlikely for a case to remain actively under consideration until it could be reviewed by the committee. Instead, appeals could expect to be resolved by the time they are reviewed by the review board. In light of the recent lack of use of the override, and the fact that most appeals are denied, the Committee proposes removing the override.

In order to accommodate cases that may need to be adjudicated urgently, the Committee proposes shortening the time frame for review of all cases to five days (compared to the current 7 days). Past review board performance indicates that most cases are closed within that time frame (See **Figure 26**), however the Committee plans to monitor to ensure that this does not significantly increase the number of exception requests closed without sufficient votes.

Figure 26: Distribution of Lung Review Board Process Times for Exceptions Requested January 1, 2021 - March 31, 2021<sup>114</sup>



Guidance related to LAS exceptions<sup>115</sup> would be retired, and new educational materials and guidance would be made available to assist lung programs in requesting exceptions and review board members in reviewing them. Proposed operational guidelines for the review board are included with this proposal as *Appendix A*. The Committee is also planning to develop additional clinical guidance and education for transplant programs submitting exception requests and review board members that will be available as a future public comment proposal.

<sup>&</sup>lt;sup>113</sup> OPTN Data as of June 8, 2021.

<sup>&</sup>lt;sup>114</sup> OPTN, Lung Review Board, HRSA Quarterly Report, April 2021.

<sup>&</sup>lt;sup>115</sup> UNOS, Submitting LAS exception requests for candidates diagnosed with PH. (Accessed June 28, 2021)

https://unos.org/news/submitting-las-exception-requests-for-candidates-diagnosed-with-ph/.



#### Feedback Requested:

- Should there be an option to list a candidate at an exception score while the appeal is pending, after the exception is denied?
- Is it appropriate to decrease the time limit for exception reviews from seven days to five days?

### **Potential Impact on Select Patient Populations**

In the current system, female candidates have lower transplant rates and a higher number of waitlist deaths than male candidates. These changes do not make a noticeable change in the transplant rate for female candidates, but they do cut the number of waitlist deaths for female candidates nearly in half, and reduce the differences in transplant rate and waiting list deaths between male and female candidates.

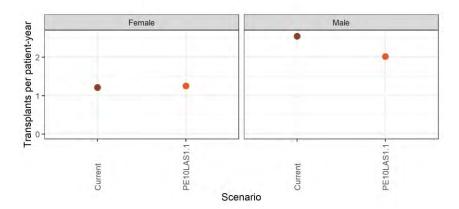
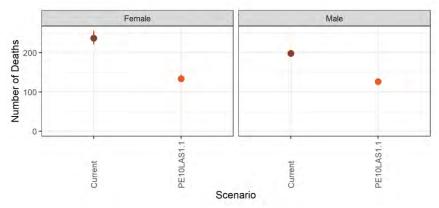


Figure 27: Transplant Rates by Sex<sup>116</sup>

<sup>116</sup> For this and following figures from this report, the labels following the pattern: "Current rules was named the "Current" scenario. Ratio of WLAUC: PTAUC was represented by "LAS1.1" or "LAS2.1", meaning 1:1 WLAUC: PTAUC and 2:1 WLAUC: PTAUC, respectively. Weight given to proximity efficiency was represented by "PE20," "PE15," and "PE10," representing 20%, 15%, and 10% PE, respectively. Thus, the scenario with 10% PE and 1:1 WLAUC: PTAUC ratios was called "PE10LAS1.1." The others follow a similar pattern." SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf.

Figure 28: Waiting List Deaths By Sex<sup>117</sup>



The transplants per patient year differed by ethnicity, with increases for Latino candidates and decreases for white and black candidates. However, the waiting list deaths still declined for all groups.

<sup>117</sup> *Ibid*.

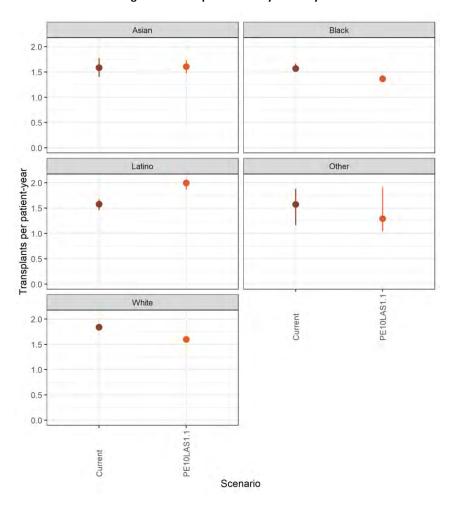


Figure 29: Transplant Rates by Ethnicity<sup>118</sup>

<sup>118</sup> *Ibid*.

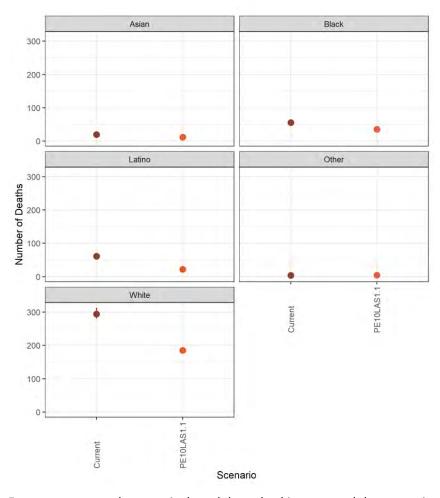


Figure 30: Waiting List Mortality by Ethnicity<sup>119</sup>

The change to a 5-year post-transplant survival model resulted in expected decreases in the transplant rate for candidates over 65 years old, who are less likely to have the longest post-transplant survival.

<sup>119</sup> *Ibid*.

350
300
250
200
150
100
50
0 -<18
18 - <35
35 - <50
50 - <65
65+

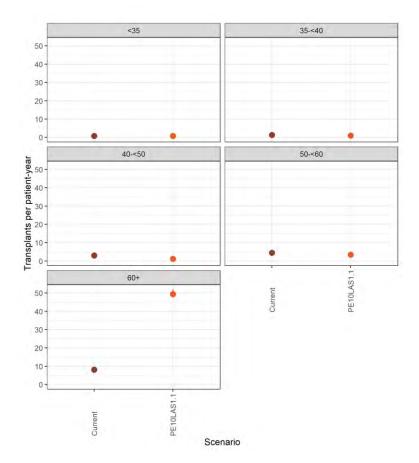
© Current 1-Year
© Current 5-Year
© Proposed 1-Year
© Proposed 5-Year

Figure 31: Transplant Rates by Age Group for 1-Year and 5-Year Post-Transplant Outcomes 120

The greatest gains in transplants per patient year and improvements in waiting list mortality are expected to be for candidates who have an LAS of 60 or higher, those most medically urgent candidates, and the differences in the other LAS groups are not as significant.

<sup>120</sup> Ibid.

Figure 32: Transplant Rates by LAS Group 121



<sup>121</sup> *Ibid*.

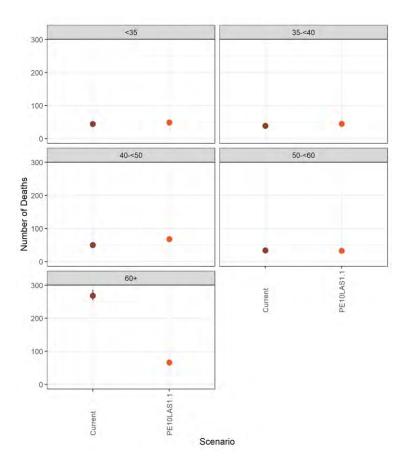


Figure 33: Waiting List Deaths by LAS Group 122

Candidates with a higher LAS are expected to receive organs from farther away in general, allowing teams to choose to travel farther for lung offers when the candidate's need is most urgent, as seen in **Figure 19** earlier.

The addition of points for candidates who have trouble finding a match due to their height brought the number of expected waiting list deaths for the tallest candidates more in line with the candidates with easier to match heights.

122 *Ibid*.

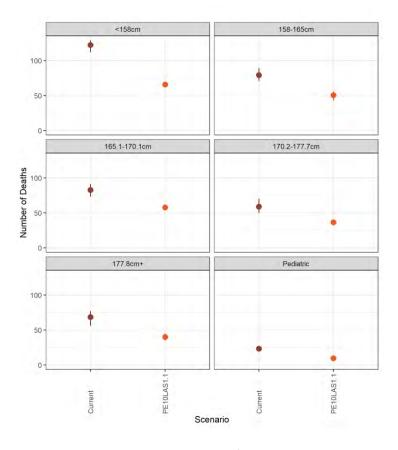


Figure 34: Waiting List Deaths by Height<sup>123</sup>

The Committee was concerned with ensuring that moving from blood type matching classifications to blood type points would assist with the challenges of matching a candidate with certain blood types. The modeling showed that placing 5% weight on blood type resulted in bringing the number of waiting list deaths for candidates with type O blood down significantly by increasing the number of transplants per patient year for this group. The impact on type O candidates is encouraging, especially since the other blood types are also expected to see a reduction in waiting list deaths.

<sup>123</sup> *Ibid*.

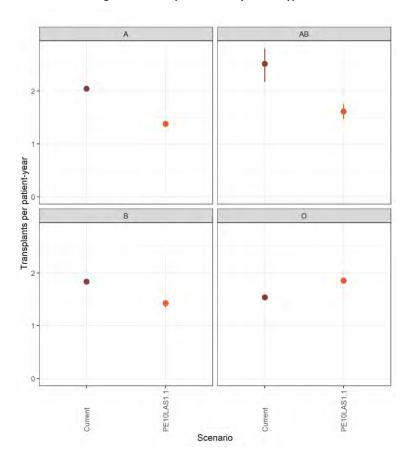


Figure 35: Transplant Rates by Blood Type<sup>124</sup>

<sup>124</sup> Ibid.

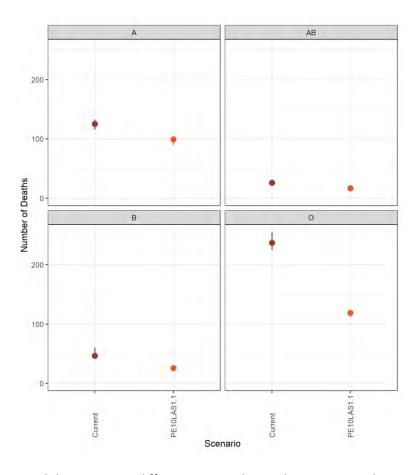


Figure 36: Waiting List Deaths by Blood Type<sup>125</sup>

The Committee reviewed the impact on different geography, evaluating impact by regon, by metropolitan and non-metropolitan area, and by center transplant volume. The proposed changes reduce variation between regions, as seen in **Figure 8** earlier.

Metropolitan areas account for most of the waiting list deaths currently, so the biggest reduction in waiting list mortality is expected in these areas, although there is also an improvement for candidates in non-metropolitan areas.

125 *Ibid*.

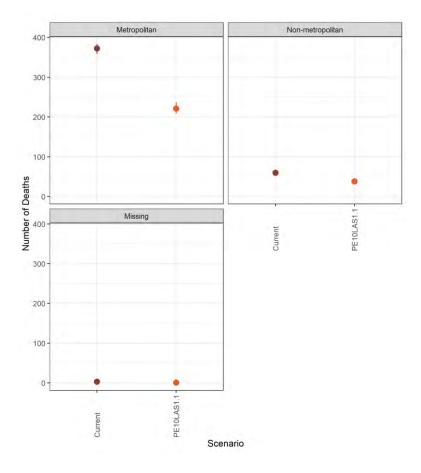


Figure 37: Waiting List Deaths by Candidate Urbanicity<sup>126</sup>

Transplant hospitals with the smallest volumes (1-15 transplants per year) are expected to receive organs that travel farther more frequently, as shown in **Figure 38**. It is worth noting that these transplant hospitals are already traveling farther than the larger centers under the current system.

<sup>126</sup> Ibid.



600
500
400
300
1-15
16-40
41-100
101+
Center volume (tx/yr)

Figure 38: Median Distance from Donor Hospital to Recipient Hospital by Annual Center Volume<sup>127</sup>

The Committee also evaluated the impact on candidates stratified by insurance status, as one proxy for socio-economic status. Waiting list mortality improved for all candidate groups, including those with Medicaid or other public insurance, as seen in **Figure 39**.

<sup>127</sup> Ibid.

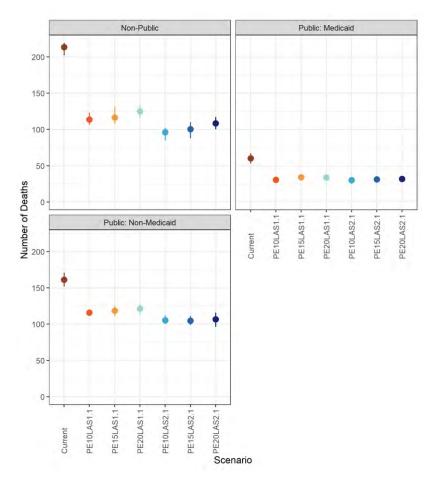


Figure 39: Waiting List Mortality by Insurance Status<sup>128</sup>

Modeling showed a potential increase in post-transplant mortality for the adolescent candidate group, corresponding with an increase in the transplant rate for this group. However, the Committee believes that this is an artifact of the fact that post-transplant mortality for pediatric lung candidates is calculated solely based on the donor age, and expects actual mortality to be lower, based on the committee's medical judgment that clinicians are likely to be more discerning about donor quality than the model shows. The Committee plans to monitor this closely.

<sup>128</sup> Ibid.

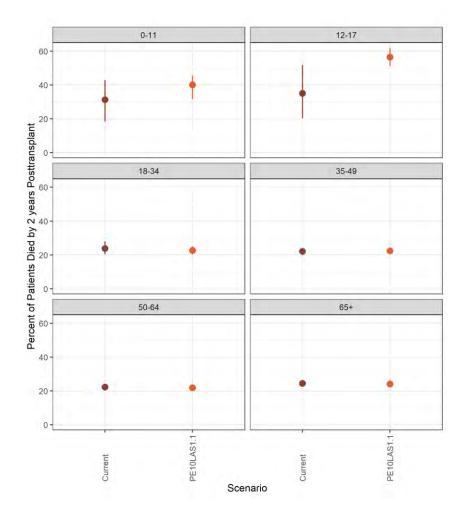


Figure 40: 2-Year Post-Transplant Mortality by Age<sup>129</sup>

### **Policy Structure**

Given the significant changes to the allocation framework used in this proposal, the order of *Policy 10: Allocation of Lungs* has been changed to accommodate the new framework. The changes are summarized in **Table 5**.

**Table 5: Crosswalk of Changed References** 

| Old Reference  | New Reference                              |
|--|--|
| 1.2 Definitions  | 1.2 Definitions                            |
| 3.6.A Waiting Time for Inactive Candidates               | 3.6.A Waiting Time for Inactive Candidates |
| 5.10.C Other Multi-Organ Combinations                    | 5.10.C Other Multi-Organ Combinations      |
| 10.1Priorities and Score Assignments for Lung Candidates | Deleted                                    |

<sup>129</sup> Ibid.



| New Reference   |
|---|
| 10.1.B.2.A Candidates Less than 12 Years Old -<br>Priority 1  |
| 10.1.2.2.B Candidates Less than 12 Years Old -<br>Priority 2  |
| 10.3 Clinical Update Schedule   |
| Deleted   |
| 10.3 Clinical Update Schedule   |
| Deleted   |
| 10.1.G Lung Disease Diagnosis Groups  |
| 21.2.A.1 PCO2 Threshold Calculation in the Waiting List Survival Calculation  |
| Deleted   |
| Deleted   |
| 10.2 Lung Composite Score Exceptions  |
| 10.2 Lung Composite Score Exceptions  |
| Deleted   |
| 10.4.A Eligibility for Intended Blood Group<br>Incompatible Offers for Deceased Donor Lungs   |
| 10.4.B Isohemagglutinin Titer Reporting<br>Requirements for a Candidate Willing to Receive<br>an Intended Blood Group Incompatible Lung |
| Deleted   |
| Deleted   |
| Deleted   |
|   |

The Committee considered whether to round place values, attempting to use sufficient place values to differentiate between candidates while also avoiding placing too much emphasis on differences that are

not indicative of a difference between candidates.<sup>130</sup> The Committee chose to allow for differences in the clinical importance of precision of different values by rounding to integers for distance, height, and days, but allowing more decimals for CPRA and other attributes, as well as for the results of equations and final scores. In this proposal, most stated values are rounded to either four, six, or ten decimal places.

The Committee is continuing to consider whether these are the appropriate lengths at which to truncate, and welcomes feedback on the usefulness and relevance of further decimal places.

#### Feedback Requested:

• How many decimal places are useful for inclusion in reference numbers and equations?

### **NOTA** and Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs." The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- Is based on sound medical judgment: The construction of the individual ratings scales and
  weights is based on objective clinical and operations evidence, including multiple rounds of
  simulation modeling, and research presented by multiple parties. The Committee also relied
  upon peer-reviewed literature as well its own clinical experience and judgment in making
  determinations regarding assigning weights and ratings to each attribute.
- Seeks to achieve the best use of donated organs: One of the best uses of a donated organ is
  that it is transplanted in the most medically urgent candidate; therefore, the proposal
  incorporates waiting list mortality as one of the attributes to be included in the candidate's
  composite allocation score. The policy was modeled by the SRTR to assess its impact on waitlist
  mortality and post-transplant outcomes and is expected to improve both compared to the
  current system.
- Is specific for each organ, in this case, lungs.

<sup>&</sup>lt;sup>130</sup> Cole T. J. (2015). Too many digits: the presentation of numerical data. *Archives of disease in childhood, 100*(7), 608–609. <a href="https://doi.org/10.1136/archdischild-2014-307149">https://doi.org/10.1136/archdischild-2014-307149</a>; Barnett, Adrian G. "Missing the Point: Are Journals Using the Ideal Number of Decimal Places?" *F1000Research 7* (August 10, 2018): 450. https://doi.org/10.12688/f1000research.14488.3.

<sup>131</sup> 42 CFR §121.4(a).

- Is designed to avoid wasting organs: The Committee does not expect impacts on organ wastage (defined as organs recovered but not transplanted).<sup>132</sup>
- Is designed to...promote patient access to transplantation: The Committee included several attributes in the proposed composite allocation score specifically to ensure that similarly situated candidates have equitable opportunities to receive an organ offer. This includes the three attributes under the goal of candidate biology (CPRA, candidate blood type, and candidate height) and the two attributes under patient access (candidate age and prior living donors). The inclusion of these attributes will increase and make more equitable access to transplantation for these patients.
- Is designed to...promote the efficient management of organ placement: The Committee considered indicators of efficiency associated with procuring and transplanting lungs, including travel costs and the proximity between the donor and transplant. Travel costs have a more direct impact on the efficiency of the organ placement system than the current geographic zones because costs are a more direct measure of efficiency than distance.
- Is not based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]: This proposal is not based on a candidate's place of registration or place of listing, except to the extent required to achieve efficient management of organ placement. The Committee used the MIT analysis so that the weight placed on efficiency (and thus the candidate's place of listing) is based on the ensuring the most benefit in the balance between waiting list and post-transplant deaths and the weight of the placement efficiency attributes.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient.<sup>133</sup>

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised. The Committee recognized that there is potential for candidates who have an exception to be treated less favorably for the period when the new system is initially implemented. The Committee recommends a transition procedure to allow exceptions to be converted, rather than just ending existing exceptions on the first day of the new system to allow time for new exception applications to be processed.

The Committee also chose to allow requests to be presented to and processed by the review board before the allocation changes take effect so that candidates with existing exceptions will have an opportunity to keep an exception on the day the new system is implemented.

This proposal also includes operational guidelines for the Lung Review Board under the authority of the Final Rule, which requires the OPTN to establish performance goals for allocation policies, including "reducing inter-transplant program variance."<sup>135</sup> The operational guidelines for the Lung Review Board are in furtherance of reduction of variation amongst transplant programs with regard to their exception requests and with regard to how the Lung Review Board reviews exception requests, to improve equity in allocation.

<sup>&</sup>lt;sup>132</sup> Although the modeling results show a lower transplant rate, they do not show a decrease in the number of transplants. The change in transplant rate is a result of an increase in waiting time for candidates who can wait longer for a transplant. SRTR, Continuous distribution simulations for lung transplant: Round 2, Data Request ID#: LU2021\_01, May 28, 2021. https://optn.transplant.hrsa.gov/media/4646/lu2021\_01\_cont\_distn\_report\_final.pdf

<sup>133</sup> 42 CFR §121.8(a)(3).

<sup>&</sup>lt;sup>134</sup> 42 C.F.R. § 121.8(d).

<sup>135 42</sup> C.F.R. §121.8(b)(4).

In addition to the allocation policy changes, this proposal recommends new data collection. The OPTN is authorized to collect data under the Final Rule, which states:

An organ procurement organization or transplant hospital shall...submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs..."<sup>1</sup> and that the OPTN shall:

- (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
- (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;
- (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and
- (iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently. 136

The new data collection included in the proposal includes various factors related to transplant candidates.

### **Implementation Considerations**

### Member and OPTN Operations

### **Operations affecting Transplant Hospitals**

Transplant hospitals will need to educate staff and patients about the changes to the allocation system, and the impact it will have on scoring, offers, exceptions, and updates to certain testing. Review board members and transplant hospitals requesting exceptions will want to familiarize themselves with the review board changes.

### Operations affecting Organ Procurement Organizations

OPOs may need to train staff on the new match run and revised multi-organ allocation rules. This proposal is also likely to alter offer patterns, and OPOs may develop new relationships with transplant hospitals they did not work with frequently in the past.

### Operations affecting Histocompatibility Laboratories

This proposal includes candidate CPRA as a factor in the composite allocation score. Histocompatibility laboratories may need to work with the lung transplant hospitals they serve to update candidate testing policies, and may be asked to test lung candidates more frequently.

#### Operations affecting the OPTN

This proposal will require extensive system changes and member education.

<sup>&</sup>lt;sup>136</sup> 42 C.F.R. §121.11(a)(1)(i)-(iv).

This proposal will require changes to UNet and the review board system. There will be limited changes to data collection related to supplemental oxygen, assisted ventilation, and prior living organ donation. As part of the review board changes, the review of exceptions will move into UNet. Existing calculated scores and exceptions will be automatically converted as part of the transition to the new system.

The OPTN plans to distribute educational materials related to the new system, including specific educational offerings related to the changes to the lung review board such as clinical exception guidance. It will also publish a new online CAS calculator and patient's guide to understanding the new composite allocation score.

This proposal may require the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule<sup>137</sup> will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, they will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

### **Projected Fiscal Impact**

This proposal is projected to have a fiscal impact on the OPTN, organ procurement organizations, transplant hospitals, and histocompatibility laboratories.

### Projected Impact on the OPTN

This proposal would require changes to UNet, including:

- A new allocation algorithm
- Adding the ability to report on a candidate's listing that they are on ECMO and clarifying the way data regarding supplemental oxygen is collected
- Moving the lung review board into UNet

The OPTN is planning to provide additional training for transplant programs and review board members, including a lung composite allocation calculator and clinical guidance for the review board.

This would be an enterprise-level change.

### Projected Impact on Organ Procurement Organizations

This proposal could have a substantial fiscal impact on organ procurement organizations (OPOs), depending on how much a continuous distribution allocation framework will require donated lungs to travel farther to potential recipients relative to the current system for allocating lungs. If lungs will routinely be traveling farther in the new allocation system, this may require OPOs to invest in new resources, like securing air transport. Anticipated workflow impacts would include longer times to allocate lungs; longer notification times to allow for farther travel by incoming recovery teams; longer case times in the donor hospital; and the possibility of late declines impacting the ability to re-allocate lungs. OPOs may need to hire additional staff or require staff to work extended hours due to longer allocation and case times. OPO staff would need to travel with local recovery teams for import

Public Comment Proposal

<sup>137 42</sup> CFR §121.11(a)(1)(i)-(iv)

recoveries on request. This proposal may impact allocation of other organs due to extended case times for allocating lungs. Implementation will require 1-4 hours for staff training.

### Projected Impact on Transplant Hospitals

The fiscal impact to transplant hospitals of implementing this proposal will vary based on how the continuous distribution allocation framework impacts travel for each center. Previous experience with the shift from Donation Service Area to 250 NM circle in lung allocation showed that the impact on transplant hospitals varied, but some transplant hospitals observed increases in travel and cost.

Transplant hospitals may experience changes in transplant volumes as a result of these changes. Transplant hospitals that experience increased volume as a result of this proposal may have additional costs for staff on call, crossmatching, and transport. Transplant hospitals that experience a decrease in volume may have difficulty recovering the lost costs via other revenue streams.

Since lungs may routinely be traveling farther for the most medically urgent candidates and staying with a smaller area for less urgent candidates in the new allocation system, transplant hospitals may need to manage increased logistical coordination and preparations for back-up candidates if they have mostly more urgent candidates. Additionally, the organ acquisition cost for lungs that travel may increase as a result of the fiscal impact on OPOs. However, for less urgent candidates, this proposal could potentially result in cost savings for transplant hospitals by achieving better utility of organs and decreasing the overall cost of care for patients, particularly those who are high priority for a lung transplant.

Implementation will require staff training on the new allocation system.

### Projected Impact on Histocompatibility Laboratories

This proposal is anticipated to have a minimal fiscal impact on histocompatibility laboratories. Since this proposal incorporates CPRA into lung allocation for the first time, histocompatibility laboratories may need to perform additional testing. However, this is not expected to result in major changes in testing volume, and allocation efficiency will improve when more transplant centers are entering unacceptable antigens for their candidates.

### **Post-implementation Monitoring**

### **Member Compliance**

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program." <sup>138</sup>

At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that lung composite allocation score clinical values reported through UNet<sup>sM</sup> are consistent with source documentation. Site surveyors will also verify that the serum creatinine and bilirubin values reported for lung candidates were the most recent results available at the time they were entered into UNet<sup>SM</sup>.

| <sup>138</sup> 42 CFR §121.8(a)(7). |  |
|-------------------------------------|--|

Member Quality staff will also continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN policy, and staff will investigate potential policy violations that are identified.

### **Policy Evaluation**

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate." Monitoring reports using pre vs. post comparisons will be presented to the Committee after approximately 3 months, 6 months and then annually for 3 years following the allocation change.

The Committee will consider overall waiting list deaths and post-transplant deaths, as well as variance in waiting list deaths, post-transplant deaths, and distance between donor and candidate transplant hospitals as key metrics to evaluate the effectiveness of the proposal.

Metrics to be evaluated include:

#### Waiting List

- Number of candidates ever waiting, additions, and removals
- Distribution of WLAUC and PTAUC
- Population characteristics such as CPRA, prior living donor, height, age group at time of listing, and diagnosis group
- Number of candidates by geographic area
- Numbers of patient deaths, overall and by diagnosis group, WLAUC and PTAUC groups, and geographic area
- Overall waiting list mortality rate and transplant rate by diagnosis group, WLAUC and PTAUC groups, and geographic area
- Number of exception requests, overall and by diagnosis group
- Number of heart-lung candidates

#### **Transplants**

- Number of recipients
- Distribution of WLAUC and PTAUC
- Population characteristics such as CPRA, prior living donor, height, age group at time of listing, and diagnosis group
- Number of recipients by geographic area
- Patient post-transplant survival
- Number of recipients transplanted with an exception requests, overall and by diagnosis group
- Distance between the donor hospital and transplant center
- Distance between the donor hospital and transplant center by medical urgency group and by composite allocation score group
- Distribution of ischemic time
- Number of heart-lung recipients

<sup>&</sup>lt;sup>139</sup> 42 CFR §121.8(a)(6).

#### **Deceased Donor Utilization**

- Discard rate by geographic area and donation after circulatory death (DCD) vs. non-DCD
- Utilization rate by geographic area and DCD vs. non-DCD
- Number & percentage of perfused lungs by geographic area
- Number & percentage of DCD lungs transplanted by geographic area
- Time from first electronic offer to cross clamp
- Distribution of sequence number of the final acceptor

Analysis of post-transplant outcomes will be performed after sufficient follow-up data has accrued, which is dependent on submission of follow-up forms. The OPTN and SRTR contractors will work with the committee to define the specific analyses requested for ongoing monitoring for each annual update. The <a href="OPTN equity in access dashboard">OPTN equity in access dashboard</a> will also be used to evaluate the impact of this policy on transplant rates by various candidate attributes.

### **Conclusion**

The Committee proposes replacing the current lung allocation framework with a composite allocation score. The lung composite allocation score would be awarded in the proportions of:

| Waitlist Survival        | 25% |
|--------------------------|-----|
| Post-transplant Outcomes | 25% |
| Biological Disadvantages | 15% |
| ABO                      | 5%  |
| CPRA                     | 5%  |
| Height                   | 5%  |
| Patient Access           | 25% |
| Pediatric                | 20% |
| Prior living donor       | 5%  |
| Placement Efficiency     | 10% |
| Travel Efficiency        | 5%  |
| Proximity Efficiency     | 5%  |

Each candidate would be awarded a portion of the score for each attribute based on their individual characteristics relative to the rating scale for that attribute.

Changes to the exception review process would be put in place in order to align with the new system and improve alignment across organs. Standards in multi-organ allocation that are currently based on LAS or distance would be replaced with references to composite allocation scores of at least 28.

The Committee is requesting feedback on the content and ideas in this paper in general, and specifically on the following questions:



#### Feedback Requested:

#### Are the weights on each attribute ideal?

- Should waitlist survival and post-transplant outcomes be equally weighted, or should waitlist survival receive twice as much weight as post-transplant outcomes?
- Is 10% the correct weight for efficiency (5% each for travel efficiency and proximity efficiency?)

#### Are the changes to exceptions appropriate?

- o Is 5 days sufficient time to allow reviewers to vote on exception applications?
- Is there a need to allow centers to list a candidate at an exception score while awaiting a decision on appeal after an initial denial?

### Are the changes to multi-organ allocation appropriate?

- o Is a composite allocation score of 28 the right cut-off?
- Does the proposal need to be adjusted to allow OPOs more discretion to offer from the heart list before offering the heart to candidates in need on the lung list who have a composite allocation score of at least 28?

How many decimal places are useful for inclusion in reference numbers and equations?



### **Policy Language**

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (<del>example</del>). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 **1.2 Definitions**

### 2 Composite allocation score (CAS)

- 3 The scoring system used to prioritize candidates on the match run. It ranges from 0-100 and is an
- 4 <u>aggregate of separate goal level scores.</u>

### 5 Lung allocation score (LAS)

The scoring system used to measure illness severity in the allocation of lungs to candidates 12 years and older.

### 7 8 9

6

### 3.6.A Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

### 11 12 13

10

#### **Table 3-3: Waiting Time for Inactive Candidates**

| If the candidate is registered for the following organ | Then the candidate accrues waiting time while inactive as follows |
|--|---|
| Heart  | No time   |
| Intestine  | Up to 30 cumulative days  |
| Kidney   | Unlimited time  |
| Kidney-pancreas  | Unlimited time  |
| Liver  | No time   |
| Lung and is at least 12 years old                      | No time Unlimited time  |
| Lung and is less than 12 years old                     | Unlimited time  |
| Pancreas   | Unlimited time  |
| Pancreas islet   | Unlimited time  |
| Any covered VCA  | Unlimited time  |
| All other organs                                       | Up to 30 days   |

### 14 15

### **5.10.E Other Multi-Organ Combinations**

When an OPO is offering a heart or lung, and a liver or kidney is also available from the same deceased donor, PTRs who meet the criteria in *Table 5-4* must be offered the second organ.

**Table 5-4 Second Organ for Heart or Lung PTRs** 

| If the OPO is<br>offering the<br>following organ: | And a PTR is also registered for one of the following organs: | The OPO must offer the second organ if the PTR is registered at a transplant hospital at or within 500 NM of the donor hospital and meets the following criteria: |
|---|---|---|
| Heart   | <del>Liver or</del><br><del>Kidney</del>                      | Heart Adult Status 1, 2, 3 or any active pediatric status   |
| Lung  | <del>Liver or</del><br><del>Kidney</del>                      | Lung allocation score of greater than or equal to 35 or candidates less than 12 years old   |

| If the OPO is offering the following organ: | And a PTR is also registered for one of the following organs: | The OPO must offer the second organ if the PTR meets all of the following criteria:  |
|---|---|--|
| <u>Heart</u>                                | <u>Liver or Kidney</u>  | <ul> <li>Registered at a transplant hospital<br/>at or within 500 NM of the donor<br/>hospital</li> <li>Heart Adult Status 1, 2, 3 or any<br/>active pediatric status</li> </ul> |
| Lung  | <u>Liver or Kidney</u>  | Has a Lung Composite Allocation Score of 28 or greater   |

- When the OPO is offering a heart or lung and two PTRs meet the criteria in *Table 5-4*, the OPO has the discretion to offer the second organ to either PTR.
- 22 It is permissible for the OPO to offer the second organ to other multi-organ PTRs that do not meet the 23 criteria above.

### 6.6.F Allocation of Heart Lungs

If a host OPO is offering a heart and a lung from the same deceased donor, then the host OPO must offer the heart and the lung according to *Policy 6.6.F.i:* Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old or Policy 6.6.F.ii: Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old.

The blood type matching requirements described in *Policy 6.6.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* apply to heart-lung candidates when the candidates appear on the lung match run.

**Public Comment Proposal** 

#### 34 6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a heart or heart-lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart-lung PTR according to *Policy 6.6.D:*Allocation of Hearts from Donors at Least 18 Years Old.

If a lung or heart-lung PTR in allocation classifications 1 through 12 according to *Policy 10.4.C:*Allocation of Lungs From Deceased Donors at Least 18 Years Old requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 4 according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer the heart and lung in the following order:

- 1. To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old
- 2. To all heart-lung PTRs with a lung composite allocation score of 28 or higher according to Policy 10.1 Allocation of Lungs
- 3. To heart PTRs in classifications 5 or later according to Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old.

The host OPO must follow the order on each the match, including heart-lung, heart, and lung candidates

### 6.6.F.ii Allocation of Heart-Lungs from Deceased Donors Less Than 18 Years Old

If a heart or heart lung potential transplant recipient (PTR) requires a lung, the OPO must offer the lungs from the same deceased donor to the heart or heart lung PTR according to *Policy 6.6.E:*Allocation of Hearts from Donors Less Than 18 Years Old.

 If a lung or heart-lung PTR in allocation classifications 1 through 10 according to *Policy 10.4.D:*Allocation of Lungs From Deceased Donors Less Than 18 Years Old requires a heart, the OPO cannot allocate the heart from the same deceased donor to the lung or heart-lung PTR until after the heart has been offered to all heart and heart-lung PTRs in allocation classifications 1 through 12 according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old.

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer:

- To all heart and heart-lung PTRs in allocation classifications 1 through 12 according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old
- To all heart-lung PTRs with a lung composite allocation score of 28 or higher according to Policy 10.1 Allocation of Lungs
- 3. To heart PTRs in classifications 13 or later according to Policy 6.6.E: Allocation of Hearts from Donors Less Than 18 Years Old

 The host OPO must follow the order on each the match, including heart-lung, heart, and lung candidates.

117

118

119120

# Policy 10: Allocation of Lungs

| 80         |  |
|------------|--|
| 81         | 10.1 Priorities and Score Assignments for Lung Candidates  |
| 82         | Lung candidates:   |
| 83         |  |
| 84         | <ul> <li>Less than 12 years old are assigned a priority for lung allocation that is based on medical urgency.</li> </ul> |
| 85         | <ul> <li>At least 12 years old use a Lung Allocation Score (LAS) to determine lung allocation, as well as</li> </ul>     |
| 86         | geography and blood type.  |
| 87         |  |
| 88         | 10.1.A Candidates Less than 12 Years Old - Priority 1  |
| 89         | A lung candidate less than 12 years old may be assigned priority 1 if at least one of the following                      |
| 90         | requirements is met:   |
| 91         |  |
| 92         | 1. Candidate has respiratory failure, evidenced by at least one of the following:  |
| 93         | <ul> <li>Requires continuous mechanical ventilation</li> </ul>   |
| 94         | <ul> <li>Requires supplemental oxygen delivered by any means to achieve FiO<sub>2</sub> greater than 50%</li> </ul>      |
| 95         | in order to maintain oxygen saturation levels greater than 90%   |
| 96         | <ul> <li>Has an arterial or capillary PCO₂ greater than 50 mm Hg</li> </ul>  |
| 97         | <ul> <li>Has a venous PCO<sub>2</sub> greater than 56 mm Hg</li> </ul>   |
| 98         |  |
| 99         | <ol><li>Pulmonary hypertension, evidenced by at least one of the following:</li></ol>                                    |
| 100        | <ul> <li>Has pulmonary vein stenosis involving 3 or more vessels</li> </ul>  |
| 101        | <ul> <li>Exhibits any of the following, in spite of medical therapy:</li> </ul>  |
| 102        |  |
| 103        | <del>○ Syncope</del>   |
| 104        | → Hemoptysis   |
| 105        | <ul> <li>Suprasystemic PA pressure on cardiac catheterization or by echocardiogram</li> </ul>                            |
| 106        | <del>estimate</del>  |
| 107        |  |
| 108        | The OPTN will maintain examples of accepted medical therapy for pulmonary hypertension.                                  |
| 109        | Transplant programs must indicate which of these medical therapies the candidate has received.                           |
| 110        | If the candidate has not received any of the listed therapies, the transplant program must                               |
| 111<br>112 | submit an exception request to the lung review board (LRB).  |
|            | 10.1 D Condidates Loss than 12 Years Old Drievity 2  |
| 113        | 10.1.B Candidates Less than 12 Years Old - Priority 2  |
| 114        | If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for                        |
| 115        | priority level 1, then the candidate is priority 2.  |
| 116        |  |

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12
Years Old

A transplant program may update the reported clinical data to justify a candidate's priority at any time. When a candidate meets the requirements for priority 1 the candidate will remain at

priority 1 for six months from the date first registered as priority 1 on the lung transplant waiting list.

To remain as priority 1, the transplant program must then update the required clinical data, except data that requires a heart catheterization, every six months following the first six months as a priority 1 candidate. The updates must occur in each six month period following the initial six months at priority 1 to remain at priority 1. The transplant program may determine the frequency of performing the heart catheterization.

If the data used to justify the priority 1 criteria are more than 6 months old at the 6-month anniversary date, other than data requiring a heart catheterization, the candidate will automatically be assigned priority 2.

Lung candidates registered on the waiting list at inactive status are subject to these same requirements for updating clinical data.

#### 10.1.D Candidates at Least 12 Years Old - LAS

Candidates who are at least 12 years old or who have an approved adolescent classification exception receive offers for deceased donor lungs based on their calculated LAS. Candidates with a higher LAS receive higher waiting list priority within geography and blood type classifications.

# 10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN clinical data corresponding with to the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six month period occurring every six months thereafter.

 A covariate's value expires if the covariate's test date is six-months older than the most recent six month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in Policy 10.2.B.iii: Estimated Values Approved by the LRB.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB.* Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN.

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal and least beneficial values that will be substituted.

Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS

| If this covariate's value:        | <del>ls:</del>                           | Then the LAS calculation will use this substituted value:                                    |
|-----------------------------------|--|--|
| Bilirubin                         | Missing, expired, or less than 0.7 mg/dL | 0.7 mg/dL  |
| Body mass index (BMI)             | Missing or expired                       | <del>100 kg/m²</del>   |
| Cardiac index                     | Missing                                  | 3.0 L/min/m <sup>2</sup>   |
| Continuous mechanical ventilation | Missing or expired                       | No mechanical ventilation in the waiting list model  |
|                                   |  | Continuous mechanical ventilation while hospitalized in the post-transplant survival measure |



| If this covariate's value: | ls:  | Then the LAS calculation will use this substituted value: |
|----------------------------|--|---|
| Creatinine: serum          | Missing or expired                         | 0.1 mg/dL in the waiting list model                       |
|                            |  | 40 mg/dL in the post-                                     |
|                            |  | transplant survival measure                               |
|                            |  | for candidates at least 18                                |
|                            |  | <del>years old</del>                                      |
|                            |  | 0 mg/dL in the post-                                      |
|                            |  | transplant survival measure                               |
|                            |  | for candidates less than 18<br>years old                  |
| Functional status          | Missing or expired                         | No assistance needed in the                               |
|                            |  | waiting list model  |
|                            |  | Some or total assistance                                  |
|                            |  | needed in the post-                                       |
|                            |  | transplant survival measure                               |
| Oxygen needed at rest      | Missing or expired                         | No supplemental oxygen needed in the waiting list         |
|                            |  | model   |
|                            |  | 26.33 L/min in the post-                                  |
|                            |  | transplant survival measure                               |
| <del>PCO</del> ₂           | Missing, expired, or less than<br>40 mm Hg | 40 mm Hg  |
| Pulmonary artery (PA)      | Missing or less than 20 mm                 | 20 mm Hg  |
| systolic pressure          | Hg   |   |
| Six-minute-walk distance   | Missing or expired                         | 4,000 feet in the waiting list                            |
|                            |  | urgency measure   |
|                            |  | O feet in the post-transplant                             |
|                            |  | survival measure  |

193 194

#### 10.1.F The LAS Calculation

195 196 The LAS calculation uses all of the following measures:

197 198  Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.

199 200  Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.

201 202 Transplant Benefit Measure, which is the difference between the Post-transplant Survival
 Measure and the Waiting List Urgency Measure.

203

204

205206

207208209

211212

213

• Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

LAS = 
$$\frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

**Table 10-2: LAS Calculation Values** 

| Where  | <del>Includes</del>  |
|--|--|
| $PTAUC = \sum_{k=0}^{364} S_{TX}(k)$   | PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year.   |
|  | β <sub>+</sub> = the coefficient for characteristic i from the waiting list measure, according to Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients.                                 |
| $S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \dots + \alpha_q Y_q}}$ | S <sub>TX</sub> (t) = the expected post-transplant survival probability at time t for an individual candidate.   |
|  | Y <sub>i</sub> = the value of the j <sup>th</sup> -characteristic for an individual candidate  |
|  | ∝ <sub>i</sub> = the coefficient for characteristic j from the post-<br>transplant survival measure, according to <i>Table 10-4</i> :<br>Post-Transplant Survival Calculation: Covariates and<br>Their Coefficients. |
| $\frac{\text{WLAUC}}{\text{WLAUC}} = \sum_{k=0}^{364} S_{\text{WL}}(k)$            | WLAUC = the area under the waiting list survival probability curve during the next year.   |



| Where   | Includes   |
|---|--|
| $S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + + \beta_p X_p}}$ | Swt.o(t) = the baseline waiting list survival probability at time t, according to Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability.  |
|   | S <sub>TX,0</sub> (t) = the baseline post-transplant survival probability at time t, according to <i>Table 10-12:</i> Baseline Post-Transplant Survival (S <sub>TX</sub> (t)) Probability. |
|   | S <sub>WL</sub> (t) = the expected waiting list survival probability at time t for an individual candidate   |
|   | X <sub>i</sub> = the value of the i <sup>th</sup> characteristic for an individual candidate.  |

215 216

217218219

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See Policy 10.1.F.i: Lung Disease Diagnosis Groups for specific information on each diagnosis group.

**Table 10 3: Waiting List Mortality Calculation: Covariates and their Coefficients** 

| For this covariate:   | The following coefficient is used in the LAS calculation:                                   |
|---|---|
| 1. Age (year)   | <del>-0.0281444188123287*age</del>  |
| 2. Bilirubin (mg/dL) value with the most recent test date and time    | -0.15572123729572*(bilirubin - 1) if bilirubin is more than 1.0 mg/dL                       |
|   | 0 when bilirubin is 1.0 mg/dL or less   |
| 3. Body mass index (BMI) (kg/m²)                                      | <del>-0.10744133677215*(20 – BMI) for BMI less than</del><br><del>20 kg/m<sup>2</sup></del> |
|   | <del>0 if BMI is at least 20 kg/m²</del>  |
| 4. Ventilation status if candidate is hospitalized                    | -1.57618530736936 if continuous mechanical ventilation needed                               |
|   | 0 if no continuous mechanical ventilation needed  |
| 5. Creatinine (serum) (mg/dL) with the most recent test date and time | -0.0996197163645* creatinine if candidate is at least 18 years old                          |
|   | 0 if candidate is less than 18 years old  |
| 6. Diagnosis Group A  | θ   |
| 7. Diagnosis Group B  | <del>1.26319338239175</del>   |
| 8. Diagnosis Group C  | <del>1.78024171092307</del>   |



| For this covariate:  | The following coefficient is used in the LAS calculation:                       |
|--|---|
| 9. Diagnosis Group D   | <del>1.51440083414275</del>   |
| 10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)  | <del>-0.40107198445555</del>  |
| 11. Detailed Diagnosis: Pulmonary fibrosis, other specify cause (Diagnosis Group D only)                 | <del>-0.2088684500011</del>   |
| 12. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only) | <del>-0.64590852776042</del>  |
| 13Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)     | <del>1.39885489102977</del>   |
| 14.  |   |
| 15. Functional Status  | -0.59790409246653 if no assistance needed with activities of daily living       |
|  | O if some or total assistance needed with activities of daily living            |
| 16. Oxygen needed to maintain adequate oxygen saturation (88%  | -0.0340531822566417*O <sub>2</sub> for Diagnosis Group B                        |
| or greater) at rest (L/min)  | $-0.08232292818591*O_2$ for Diagnosis Groups A, C, and D                        |
| 17PCO <sub>2</sub> -(mm-Hg): current   | -0.12639905519026*PCO <sub>2</sub> /10 if PCO <sub>2</sub> is at least 40 mm Hg |
| 18. PCO <sub>2</sub> increase of at least 15%  | -0.15556911866376 if PCO <sub>2</sub> -increase is at least 15%                 |
|  | 0 if PCO <sub>2</sub> increase is less than 15%                                 |
| 19. Pulmonary artery (PA) systolic   | -0.55767046368853*(PA systolic – 40)/10 for                                     |
| pressure (10 mm Hg) at rest, prior   | Diagnosis Group A if the PA systolic pressure is                                |
| to any exercise  | greater than 40 mm Hg   |
|  | 0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less         |
|  | O.1230478043299*PA systolic/10 for Diagnosis<br>Groups B, C, and D              |

| For this covariate:   | The following coefficient is used in the LAS calculation: |
|---|---|
| 20. Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test. | -0.09937981549564*Six-minute-walk<br>distance/100         |

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

**Table 10 4: Post Transplant Survival Calculation: Covariates and Their Coefficients** 

| For this covariate:  | The following is used in the LAS calculation:                          |
|--|--|
| 1. Age (years)   | -0.0208895939056676*(age-45) if candidate is greater than 45 years old |
|  | 0 if candidate is 45 years old or younger                              |
| 2. Creatinine (serum) at transplant (mg/dL) with the most recent data and time               | 0.25451764981323*creatinine if candidate is at least 18 years old      |
|  | 0 if candidate is less than 18 years old                               |
| 3. Cardiac index (L/min/m²) at rest, prior to any exercise                                   | -0.1448727551614 if less than 2 L/min/m <sup>2</sup>                   |
| ·  | 0 if at least 2 L/min/m <sup>2</sup>                                   |
| 4. Ventilation status if candidate is  | -0.33161555489537 if continuous  |
| <del>hospitalized</del>  | mechanical ventilation needed  |
|  | 0 if no continuous mechanical ventilation needed                       |
| 5. Diagnosis Group B   | - <del>0.51341349576197</del>  |
| 6. Diagnosis Group C   | <del>-0.23187885123342</del>   |
| 7. Diagnosis Group D   | -0.12527366545917  |
| 8. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)                               | <del>-0.12048575705296</del>   |
| 9.—Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only) | <del>-0.33402539276216</del>   |

| For this covariate:   | The following is used in the LAS calculation:               |
|---|---|
| 10. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)  | <del>-0.43537371336129</del>                                |
| 11. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)  | <del>-0.98051166673574</del>                                |
| 12. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)   | -0.0100383613234584*O <sub>2</sub> for Diagnosis<br>Group A |
|   | -0.0093694370076423*O₂ for Diagnosis<br>Groups B, C, and D  |
| 13. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to   | -0.0001943695814883*(1200-Six-minute-<br>walk distance)     |
| maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the | 0 if six-minute-distance-walked is at least<br>1,200 feet   |
| <del>test.</del>  |   |

226227

See Policy 10.5: Probability Data Used in the LAS Calculation for Tables 10-11 and 10-12 that provide data used in the LAS calculation.

228229230

#### 10.1.F.i Lung Disease Diagnosis Groups

231

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

232233

#### Group A

234235

A candidate is in Group A if the candidate has any of the following diagnoses:

236237

Allergic bronchopulmonary aspergillosis
 Alpha-1 antitrypsin deficiency

238

Aipna-1 antitrypsin dentiency
 Bronchiectasis

239

Bronchopulmonary dysplasia

240241

• Chronic obstructive pulmonary disease/emphysema

241242

Ehlers-Danlos syndrome

243

Granulomatous lung disease
 Inhalation burns/trauma

244

• Kartagener's syndrome

245

• Lymphangioleiomyomatosis

246247

Obstructive lung diseasePrimary ciliary dyskinesia;

248

Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less

249

• Tuberous sclerosis

| 250 | <ul> <li>Wegener's granuloma – bronchiectasis</li> </ul>                           |
|-----|--|
| 251 |  |
| 252 | Group B  |
| 253 | A candidate is in Group B if the candidate has any of the following diagnoses:     |
| 254 |  |
| 255 | <ul> <li>Congenital malformation</li> </ul>  |
| 256 | <ul> <li>CREST – pulmonary hypertension</li> </ul>                                 |
| 257 | <ul> <li>Eisenmenger's syndrome: atrial septal defect (ASD)</li> </ul>             |
| 258 | <ul> <li>Eisenmenger's syndrome: multi-congenital anomalies</li> </ul>             |
| 259 | <ul> <li>Eisenmenger's syndrome: other specify</li> </ul>                          |
| 260 | <ul> <li>Eisenmenger's syndrome: patent ductus arteriosus (PDA)</li> </ul>         |
| 261 | <ul> <li>Eisenmenger's syndrome: ventricular septal defect (VSD)</li> </ul>        |
| 262 | <ul> <li>Portopulmonary hypertension</li> </ul>                                    |
| 263 | <ul> <li>Primary pulmonary hypertension/pulmonary arterial hypertension</li> </ul> |
| 264 | <ul> <li>Pulmonary capillary hemangiomatosis</li> </ul>                            |
| 265 | <ul> <li>Pulmonary telangiectasia – pulmonary hypertension</li> </ul>              |
| 266 | <ul> <li>Pulmonary thromboembolic disease</li> </ul>                               |
| 267 | <ul> <li>Pulmonary vascular disease</li> </ul>                                     |
| 268 | <ul> <li>Pulmonary veno-occlusive disease</li> </ul>                               |
| 269 | <ul> <li>Pulmonic stenosis</li> </ul>  |
| 270 | <ul> <li>Right hypoplastic lung</li> </ul>   |
| 271 | <ul> <li>Scleroderma – pulmonary hypertension</li> </ul>                           |
| 272 | <ul> <li>Secondary pulmonary hypertension</li> </ul>                               |
| 273 | <ul> <li>Thromboembolic pulmonary hypertension</li> </ul>                          |
| 274 |  |
| 275 | Group C  |
| 276 | A candidate is in Group C if the candidate has any of the following diagnoses:     |
| 277 |  |
| 278 | <ul> <li>Common variable immune deficiency</li> </ul>                              |
| 279 | <ul> <li>Cystic fibrosis</li> </ul>  |
| 280 | <ul> <li>Fibrocavitary lung disease</li> </ul>                                     |
| 281 | <ul> <li>Hypogammaglobulinemia</li> </ul>  |
| 282 | <ul> <li>Schwachman-Diamond syndrome</li> </ul>                                    |
| 283 |  |
| 284 | Group D  |
| 285 | A candidate is in Group D if the candidate has any of the following diagnoses:     |
| 286 |  |
| 287 | <ul> <li>ABCA3 transporter mutation</li> </ul>                                     |
| 288 | <ul> <li>Alveolar proteinosis</li> </ul>   |
| 289 | <ul> <li>Amyloidosis</li> </ul>  |
| 290 | <ul> <li>Acute respiratory distress syndrome or pneumonia</li> </ul>               |
| 291 | Bronchioloalveolar carcinoma (BAC)   |
| 292 | <ul> <li>Carcinoid tumorlets</li> </ul>  |
| 293 | <ul> <li>Chronic pneumonitis of infancy</li> </ul>                                 |
| 294 | <ul> <li>Constrictive bronchiolitis</li> </ul>                                     |
| 295 | <ul> <li>COVID-19: acute respiratory distress syndrome</li> </ul>                  |

| 296 | <ul> <li>COVID-19: pulmonary fibrosis</li> </ul>  |
|-----|---|
| 297 | <ul> <li>CREST – Restrictive</li> </ul>   |
| 298 | Eosinophilic granuloma  |
| 299 | <ul> <li>Fibrosing Mediastinitis</li> </ul>   |
| 300 | <ul> <li>Graft versus host disease (GVHD)</li> </ul>  |
| 301 | Hermansky Pudlak syndrome   |
| 302 | <ul> <li>Hypersensitivity pneumonitis</li> </ul>  |
| 303 | <ul> <li>Idiopathic interstitial pneumonia, with at least one or more of the following</li> </ul> |
| 304 | disease entities:   |
| 305 | <ul> <li>Acute interstitial pneumonia</li> </ul>  |
| 306 | <ul> <li>Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing</li> </ul>     |
| 307 | <del>pneumonia (BOOP)</del>   |
| 308 | <ul> <li>Desquamative interstitial pneumonia</li> </ul>   |
| 309 | → Idiopathic pulmonary fibrosis (IPF)   |
| 310 | <ul> <li>Nonspecific interstitial pneumonia</li> </ul>  |
| 311 | <ul> <li>Lymphocytic interstitial pneumonia (LIP)</li> </ul>                                      |
| 312 | <ul> <li>Respiratory bronchiolitis-associated interstitial lung disease</li> </ul>                |
| 313 | <ul> <li>Idiopathic pulmonary hemosiderosis</li> </ul>  |
| 314 | <ul> <li>Lung retransplant or graft failure: acute rejection</li> </ul>                           |
| 315 | <ul> <li>Lung retransplant or graft failure: non-specific</li> </ul>                              |
| 316 | <ul> <li>Lung retransplant or graft failure: obliterative bronchiolitis-obstructive</li> </ul>    |
| 317 | <ul> <li>Lung retransplant or graft failure: obliterative bronchiolitis-restrictive</li> </ul>    |
| 318 | <ul> <li>Lung retransplant or graft failure: obstructive</li> </ul>                               |
| 319 | <ul> <li>Lung retransplant or graft failure: other specify</li> </ul>                             |
| 320 | <ul> <li>Lung retransplant or graft failure: primary graft failure</li> </ul>                     |
| 321 | <ul> <li>Lung retransplant or graft failure: restrictive</li> </ul>                               |
| 322 | • Lupus   |
| 323 | <ul> <li>Mixed connective tissue disease</li> </ul>   |
| 324 | <ul> <li>Obliterative bronchiolitis: non-retransplant</li> </ul>                                  |
| 325 | <ul> <li>Occupational lung disease: other specify</li> </ul>                                      |
| 326 | <ul> <li>Paraneoplastic pemphigus associated Castleman's disease</li> </ul>                       |
| 327 | <ul> <li>Polymyositis</li> </ul>  |
| 328 | <ul> <li>Pulmonary fibrosis: other specify cause</li> </ul>                                       |
| 329 | <ul> <li>Pulmonary hyalinizing granuloma</li> </ul>   |
| 330 | <ul> <li>Pulmonary lymphangiectasia (PL)</li> </ul>   |
| 331 | <ul> <li>Pulmonary telangiectasia – restrictive</li> </ul>  |
| 332 | <ul> <li>Rheumatoid disease</li> </ul>  |
| 333 | <ul> <li>Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg</li> </ul>          |
| 334 | <ul> <li>Scleroderma – restrictive</li> </ul>   |
| 335 | <ul> <li>Secondary pulmonary fibrosis: (specify cause)</li> </ul>                                 |
| 336 | • Silicosis   |
| 337 | <ul> <li>Sjogren's syndrome</li> </ul>  |
| 338 | <ul> <li>Surfactant protein B mutation</li> </ul>   |
| 339 | Surfactant protein C mutation   |
| 340 | • Teratoma  |
| 341 | <ul> <li>Wegener's granuloma – restrictive</li> </ul>   |

| <del>10.</del> 1 | L.F.ii PCO2 in the LAS   |
|------------------|--|
|                  | The LAS calculation uses two measures of PCO <sub>2</sub> :  |
|                  |  |
|                  | 1.—Current PCO₂  |
|                  | 2.—PCO <sub>2</sub> Threshold Change   |
|                  | ·  |
|                  | Current PCO₂   |
|                  | Current PCO2 is the PCO2 value reported to the OPTN with the most recent test date                         |
|                  | and time. A program may report a PCO <sub>2</sub> value from an arterial, venous, or capillary             |
|                  | blood gas test. All blood gas values will be converted to an arterial value as follows:                    |
|                  |  |
|                  | <ul> <li>A capillary value will equal an arterial value.</li> </ul>  |
|                  | <ul> <li>A venous value minus 6 mmHg equals an arterial value.</li> </ul>                                  |
|                  |  |
|                  | PCO <sub>2</sub> -Threshold-Change   |
|                  | There are two PCO₂threshold change calculations:   |
|                  |  |
|                  | ◆ The PCO₂ Threshold Change Calculation  |
|                  | <ul> <li>The Threshold Change Maintenance Calculation</li> </ul>   |
|                  |  |
|                  | The PCO <sub>2</sub> Threshold Change Calculation  |
|                  | An increase in PCO <sub>2</sub> that is at least 15% will impact a candidate's LAS. If a value is          |
|                  | less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg                         |
|                  | before calculating change. The PCO <sub>2</sub> threshold change calculation uses the highest              |
|                  | and lowest values of PCO <sub>2</sub> as follows:  |
|                  |  |
|                  | <ul> <li>The test date and time of the lowest value reported to the OPTN used in the</li> </ul>            |
|                  | PCO <sub>2</sub> threshold change calculation must be earlier than the test date and time                  |
|                  | of the highest value used in the PCO <sub>2</sub> threshold change calculation.                            |
|                  | <ul> <li>Test dates of these highest and lowest values cannot be more than six months</li> </ul>           |
|                  | <del>apart.</del>  |
|                  | <ul> <li>The PCO<sub>2</sub> threshold change calculation can use an expired lowest value, but</li> </ul>  |
|                  | cannot use an expired highest value.   |
|                  |  |
|                  | If a current PCO <sub>2</sub> value expires according to Policy 10.1.E: LAS Values and Clinical            |
|                  | Data Update Schedule for Candidates at Least 12 Years Old, the candidate's LAS will                        |
|                  | lose the impact from the PCO <sub>2</sub> threshold change calculation. The equation for the               |
|                  | PCO₂ threshold change calculation is:  |
|                  | Highost BCO Lowest BCO   |
|                  | Highest PCO <sub>2</sub> .— Lowest PCO <sub>2</sub> Lowest PCO <sub>2</sub>                                |
|                  | <del>LUWUSE MUU-</del>   |
|                  | The Threshold Change Maintenance Calculation   |
|                  | When a 15% or greater PCO <sub>2</sub> threshold change calculation impacts a candidate's LAS <sub>1</sub> |
|                  | the LAS threshold change maintenance calculation assesses whether to maintain                              |
|                  |  |

387 that impact. To maintain the impact of the PCO<sub>2</sub> increase, the candidate's current 388 PCO2 value must be at least 15% higher than the lowest value used in the PCO2 389 threshold change calculation. The equation for this threshold change maintenance 390 calculation is: 391 392 393 394 The threshold change maintenance calculation occurs either when the current PCO2 395 value expires, according to Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old, or a new current PCO2 value is 396 397 entered. For this calculation, the lowest and highest values that were used in the 398 PCO2 threshold change calculation can be expired. The current PCO2 value can be the 399 highest one that was used in the PCO2 threshold change calculation. If a current 400 PCO2 value expires, the candidate's LAS will no longer be affected by the PCO2 401 threshold change. 402 403 If a transplant hospital reports a new current PCO2 value for a candidate who has 404 lost the impact from the PCO2 threshold change calculation, the LAS will perform the 405 threshold change maintenance calculation. If the new current PCO2 value is at least 406 15% higher than the lowest value used in the PCO2 threshold change calculation, the candidate's LAS will again be affected by the PCO<sub>2</sub> threshold change calculation. 407 408 409 Normal PCO2 Value 410 The normal clinical PCO2 value is 40mmHg. If a current PCO2 value is below 40 mmHg, or if the current PCO2 value is missing or expired, the LAS calculation will use 411 the normal clinical PCO2 value. 412 413 414 10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher 415 Within 14 days of the date a candidate's LAS becomes 50 or higher, the candidate's transplant program must assess and report to the OPTN the following variables: 416 417 418 1.—Assisted ventilation 419 2.—Supplemental oxygen 420 Current PCO₂ 421 422 While the candidate's LAS remains 50 or higher, the transplant program must continue to assess 423 and report assisted ventilation and supplemental oxygen data every 14 days. The transplant 424 program is only required to report updated PCO2 data if the assessment was performed during 425 the previous 14 day interval. 426 427 The transplant program must maintain documentation of each assessment in the candidate's 428 medical chart. 429



### **10.2 Priority and Score Exceptions**

#### 10.2.A Allocation Exception for Highly Sensitized Patients

A lung candidate's transplant physician may use medical judgment to determine that a lung candidate is highly sensitized.

If there is one or more lung transplant programs that have potential transplant recipients (PTRs) who appear on the match run above the highly sensitized candidate, then the highly sensitized candidate's transplant program may request that those transplant programs refuse the offer so that the transplant program can accept the offer for the highly sensitized candidate.

If the only PTRs on the match run are registered at the same transplant program as the highly sensitized candidate, the transplant physician may use medical judgment to accept the offer for the highly sensitized candidate out of sequence.

#### 10.2.B Lung Candidates with Exceptional Cases

The Lung Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate's transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of *Policy 10.4.C:* Allocation of Lungs from Deceased Donors at Least 18 Years Old and Policy 10.4.D: Allocation of Lungs from Deceased Donors Less than 18 Years Old. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.D:* Allocation of Lungs from Deceased Donors Less than 18 Years Old.

#### 10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis,

estimated value, or adolescent classification, and the OPTN will send the request or appeal to the Lung Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.

#### 10.2.B.ii LRB Decision Overrides

If the LRB denies a transplant hospital's initial request or appeal for an estimated value, adolescent classification, or specific LAS on appeal, the transplant hospital has the option to override the decision of the LRB. If the transplant hospital elects to override the decision of the LRB, then the OPTN will send the request or appeal to the Lung Transplantation Committee for review. This review by the Lung Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee (MPSC). If the MPSC agrees with the Lung Transplantation Committee's decision, a member who has registered a candidate with an unapproved estimated value, adolescent classification, or LAS will be subject to action according to Appendix M: Reviews and Actions of the OPTN Bylaws.

#### 10.2.B.iii Estimated Values Approved by the LRB

Approved estimated values approved by the LRB or Lung Transplantation Committee are valid until an actual value is reported to the OPTN or a new estimated value is reported to the OPTN.

#### 10.2.B.iv LAS Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Lung Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.

#### 10.2.B.v LAS Approved by the LRB

An LAS approved by the LRB or the Lung Transplantation Committee will remain valid for six months from the date the candidate's LAS is updated, (or from the candidate's twelfth birthday, whichever occurs later). If the candidate is still on the waiting list six months after the date the LAS is updated, then the candidate's LAS will be computed as described in Policy 10.1: Priorities and Score Assignments for Lung Candidates unless a new LAS or priority request is submitted to the OPTN.

### **10.3 Waiting Time**

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

| 517 | When waiting time is used for lung allocation, a candidate will receive a preference over other       |
|-----|---|
| 518 | candidates who have accumulated less waiting time within the same priority or LAS.                    |
| 519 |   |
| 520 | 10.3.A Lung Candidates at Least 12 Years Old  |
| 521 | If multiple candidates have identical computed LASs greater than zero, and have identical             |
| 522 | priority for a lung offer considering all other allocation factors, then priority among those         |
| 523 | candidates will be determined by the earliest date and time of each candidate's most recent           |
| 524 | data used in the calculation of the LAS reported to the OPTN.   |
| 525 |   |
| 526 | If multiple candidates have identical assigned LASs due to an exceptional case request as             |
| 527 | defined by Policy 10.2.B, and have identical priority for a lung offer considering all other          |
| 528 | allocation factors, then priority among those candidates will be determined by the earliest date      |
| 529 | and time that each candidate's most recent LRB approval of that LAS was reported to the OPTN.         |
| 530 |   |
| 531 | 10.3.B Lung Candidates Less than 12 Years Old   |
| 532 | Allocation ranking for a priority 1 lung candidate is based on the candidate's most recent priorit    |
| 533 | 1 waiting time, which only includes the candidate's current time as priority 1 and does not           |
| 534 | include any previous time spent as priority 1.  |
| 535 |   |
| 536 | If there is ever a tie among priority 1 candidates within the same classification due to identical    |
| 537 | priority 1 waiting times, then the lung will be allocated to the priority 1 candidate with the most   |
| 538 | total waiting time. Total waiting time includes time spent waiting as priority 1, priority 2, and at  |
| 539 | inactive status. Allocation ranking will also consider this total waiting time.                       |
| 540 |   |
| 541 | Among priority 2 candidates, allocation ranking considers total waiting time for receiving            |
| 542 | deceased donor lung offers. Total waiting time includes the time a candidate spent waiting as         |
| 543 | priority 1, priority 2, and inactive. A priority 2 lung candidate's waiting time is the same as total |
| 544 | waiting time.   |
| 545 |   |
| 546 | 10.4 Lung Allocation Classifications and Rankings   |
| 547 | 10.4.A Sorting Within Each Classification   |
| 548 | Lung candidates at least 12 years old are sorted in the following order:                              |
| 549 |   |
| 550 | 1. LAS (highest to lowest)  |
| 551 | 2.—Total active waiting time (longest to shortest)  |
| 552 | <ol><li>LAS variable update date and time (earliest to most recent approval)</li></ol>                |
| 553 | <ol> <li>LAS exception date (earliest to most recent approval)</li> </ol>                             |
| 554 |   |
| 555 | Lung candidates less than 12 years old are sorted in the following order:                             |
| 556 |   |
| 557 | <ol> <li>Pediatric priority waiting time (longest to shortest)</li> </ol>                             |
| 558 | 2. Total waiting time (longest to shortest)   |
| 559 |   |



#### 10.4.B Allocation of Lungs by Blood Type

A deceased donor's blood type compatibility with a lung candidate is defined in *Table 10-5* below.

563 564

560

561

562

Table 10 5: Deceased Donor Blood Type Compatibility with a Lung Candidate

| Deceased Donor's | Candidate's Blood Type |                      |                      |                      |
|------------------|------------------------|----------------------|----------------------|----------------------|
| Blood Type       | 0                      | A                    | B                    | AB                   |
| 0                | <del>Identical</del>   | Compatible           | Compatible           | Compatible           |
| A                | <del>Screened*</del>   | <del>Identical</del> | Screened*            | Compatible           |
| B                | <del>Screened*</del>   | <del>Screened*</del> | <del>Identical</del> | Compatible           |
| AB               | Screened*              | Screened*            | Screened*            | <del>Identical</del> |

<sup>\*</sup>Screened from match run, unless eligible for intended blood group incompatible offers according to *Policy 10.4.B.i* 

566567568

565

# 10.4.B.i Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

570 571

569

Candidates will be eligible for intended blood group incompatible deceased donor lungs if they meet the requirements according to *Table 10-6* below.

572573574

Table 10-6: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

| If the candidate is:          | And meets all of the following:             |
|-------------------------------|---|
| Less than one year old at the | 1.—Is priority 1.                           |
| time of the match run         | 2. Has reported isohemagglutinin titer      |
|                               | information for A or B blood type antigens  |
|                               | to the OPTN within the last 30 days.        |
| At least one year old at the  | 1.—Is registered prior to turning two years |
| time of the match run         | <del>old.</del>                             |
|                               | 2. Is priority 1.                           |
|                               | 3. Has reported to the OPTN                 |
|                               | isohemagglutinin titers less than or equal  |
|                               | to 1:16 for A or B blood type antigens      |
|                               | from a blood sample collected within the    |
|                               | last 30 days. The candidate must not have   |
|                               | received treatments that may have           |
|                               | reduced isohemagglutinin titers to 1:16 or  |
|                               | less within 30 days of when this blood      |
|                               | sample was collected.                       |



# 10.4.B.ii Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood group incompatible lung, according to *Table 10-7* below, at *all* of the following times:

- 4. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible lung.
- 5. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible lung.

Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

| If the candidate's blood type is: | Then the transplant program must report the following isohemagglutinin titers to the OPTN: |
|-----------------------------------|--|
| A                                 | Anti-B   |
| B                                 | Anti A   |
| 0                                 | Anti-A and Anti-B  |

Accurate isohemagglutinin titers must be reported for recipients of an intended blood group incompatible lung, according to *Table 10-8*, as follows:

- 1.—At transplant, from a blood sample taken within 24 hours prior to transplant.
- 2. If graft loss occurs within one year after transplant from the most recent sample, if available.
- 3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Group Incompatible Lung

| If the deceased<br>donor's blood type<br>is: | And the recipient's blood type is: | Then the transplant program must report the following isohemagglutinin titers to the OPTN: |
|--|------------------------------------|--|
| A  | <del>B or O</del>                  | Anti-A   |
| ₽  | A or O                             | Anti-B   |
| AB   | A                                  | Anti-B   |
| AB   | B                                  | Anti-A   |
| AB   | θ                                  | Anti-A and Anti-B  |



605

606

607 608

### 10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-9* below.

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

| Classification   | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |
|--|---|--|--|--|
| 1  | At least 12 years old, blood<br>type identical to the donor   | -250NM   |  |  |
| 2  | At least 12 years old, blood<br>type compatible with the donor  | -250NM   |  |  |
| 3  | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | <del>-250NM</del>  |  |  |
| Priority 1 and one of the following:  At least 1 year old and bloo type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers |   | - <del>250NM</del>   |  |  |
| 5  | Priority 2, blood type identical to the donor   | -250NM   |  |  |
| 6  | Priority 2, blood type compatible with the donor  | -250NM   |  |  |
| 7  | At least 12 years old, blood type identical to the donor  | - <del>500NM</del>   |  |  |
| 8  | At least 12 years old, blood<br>type compatible with the donor  | - <del>500NM</del>   |  |  |



| Classification  | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |
|---|---|--|--|--|
| 9   | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | - <del>500NM</del>   |  |  |
| <del>10</del>   | Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers   | -500NM   |  |  |
| 11  | Priority 2, blood type identical to the donor   | -500NM   |  |  |
| <del>12</del>   | Priority 2, blood type compatible with the donor  | -500NM   |  |  |
| <del>13</del>   | At least 12 years old, blood<br>type identical to the donor   | -1000NM  |  |  |
| 14  | At least 12 years old, blood type compatible with the donor   | -1000NM  |  |  |
| Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers |   | -1000NM  |  |  |



| Classification  | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |
|---|---|--|
| <del>16</del>   | Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers   | -1000NM  |
| <del>17</del>   | Priority 2, blood type identical to the donor   | -1000NM  |
| <del>18</del>   | Priority 2, blood type compatible with the donor  | -1000NM  |
| <del>19</del>   | At least 12 years old, blood<br>type identical to the donor   | -1500NM  |
| <del>20</del>   | At least 12 years old, blood<br>type compatible with the donor  | -1500NM  |
| 21  | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | -1500NM  |
| Priority 1 and one of the following:  • At least 1 year old and blood type compatible with the donor  • At least 1 year old and eligible for intended blood group incompatible offers |   | -1500NM  |
| 23  | Priority 2, blood type identical to the donor   | -1500NM  |
| 24  | Priority 2, blood type compatible with the donor  | -1500NM  |



| Classification  | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |
|---|---|--|
| <del>25</del>   | At least 12 years old, blood<br>type identical to the donor   | -2500NM  |
| <del>26</del>   | At least 12 years old, blood<br>type compatible with the donor  | - <del>2500NM</del>  |
| <del>27</del>   | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | -2500NM  |
| 28  | Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers   | -2500NM  |
| <del>29</del>   | Priority 2, blood type identical to the donor   | -2500NM  |
| <del>30</del>   | Priority 2, blood type compatible with the donor  | -2500NM  |
| <del>31</del>   | At least 12 years old, blood<br>type identical to the donor   | Nation   |
| At least 12 years old, blood type compatible with the donor |   | - <del>Nation</del>  |



| Classification                                   | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |
|--|---|--|--|--|
|  | Priority 1 and one of the following:  |  |  |  |
| 33   | <ul> <li>Less than 12 years old and<br/>blood type identical to the<br/>donor</li> </ul>  |  |  |  |
| <del>55</del>                                    | <ul> <li>Less than 1 year old and<br/>blood type compatible with<br/>the donor</li> </ul>   | Nation   |  |  |
|  | <ul> <li>Less than 1 year old and<br/>eligible for intended blood<br/>group incompatible offers</li> </ul>                        |  |  |  |
|  | Priority 1 and one of the following:  |  |  |  |
| 34   | At least 1 year old and blood     type compatible with the     donor      At least 1 year old and     eligible for intended blood |  |  |  |
|  | group incompatible offers   |  |  |  |
| Priority 2, blood type identical to the donor    |   | - Nation   |  |  |
| Priority 2, blood type compatible with the donor |   | Nation   |  |  |

611

### 10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old

Single and double lungs from deceased donors less than 18 years old are allocated according to *Table 10-10* below.

612613

614 Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old

|                | 10-10: Allocation of Lungs from Deceased Do   |  |
|----------------|---|--|
| Classification | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |
| 1              | Priority 1 and one of the following:  | -1000NM  |
|                | <ul> <li>Less than 12 years old and blood type identical to the donor</li> <li>Less than 1 year old and blood type compatible with the donor</li> <li>Less than 1 year old and eligible for intended blood group incompatible offers</li> </ul> |  |
| 2              | Priority 1 and one of the following:  • At least 1 year old and blood type compatible with the donor  • At least 1 year old and eligible for intended blood group incompatible offers   | -1000NM  |
| 3              | Priority 2, blood type identical to the donor   | -1000NM  |
| 4              | Priority 2, blood type compatible with the donor  | -1000NM  |
| 5              | 12 to less than 18 years old, blood type identical to the donor   | -1000NM  |
| 6              | 12 to less than 18 years old, blood type compatible with the donor  | -1000NM  |
| 7              | At least 18 years old, blood type identical to the donor  | -250NM   |
| 8              | At least 18 years old, blood type compatible with the donor   | -250NM   |
| 9              | At least 18 years old, blood type identical to the donor  | -500NM   |
| <del>10</del>  | At least 18 years old, blood type compatible with the donor   | -500NM   |
| 11             | At least 18 years old, blood type identical to the donor  | -1000NM  |
| 12             | At least 18 years old, blood type compatible with the donor   | -1000NM  |



| Classification | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |  |  |
|----------------|---|--|--|--|--|--|
| <del>13</del>  | Priority 1 and one of the following:  | -1500NM  |  |  |  |  |
|                | Less than 12 years old and blood type identical to the donor     Less than 1 year old and blood         |  |  |  |  |  |
|                | type compatible with the donor  |  |  |  |  |  |
|                | Less than 1 year old and eligible for intended blood group incompatible offers                          |  |  |  |  |  |
| <del>14</del>  | Priority 1 and one of the following:  | -1500NM  |  |  |  |  |
|                | At least 1 year old and blood<br>type compatible with the<br>donor     At least 1 year old and eligible |  |  |  |  |  |
|                | for intended blood group incompatible offers  |  |  |  |  |  |
| <del>15</del>  | Priority 2, blood type identical to the donor   | -1500NM  |  |  |  |  |
| <del>16</del>  | Priority 2, blood type compatible with the donor  | -1500NM  |  |  |  |  |
| <del>17</del>  | 12 to less than 18 years old,<br>blood type identical to the donor                                      | -1500NM  |  |  |  |  |
| <del>18</del>  | 12 to less than 18 years old,<br>blood type compatible with the<br>donor                                | <del>1500NM</del>  |  |  |  |  |
| 19             | At least 18 years old, blood type identical to the donor  | -1500NM  |  |  |  |  |
| <del>20</del>  | At least 18 years old, blood type compatible with the donor   | -1500NM  |  |  |  |  |



| Classification | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |  |  |
|----------------|---|--|--|--|--|--|
| 21             | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | -2500NM  |  |  |  |  |
| <del>22</del>  | Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers   | -2500NM  |  |  |  |  |
| 23             | Priority 2, blood type identical to the donor   | -2500NM  |  |  |  |  |
| <del>2</del> 4 | Priority 2, blood type compatible with the donor  | <del>-2500NM</del>   |  |  |  |  |
| <del>25</del>  | 12 to less than 18 years old,<br>blood type identical to the donor  | -2500NM  |  |  |  |  |
| <del>26</del>  | 12 to less than 18 years old,<br>blood type compatible with the<br>donor  | <del>-2500NM</del>   |  |  |  |  |
| <del>27</del>  | At least 18 years old, blood type identical to the donor  | -2500NM  |  |  |  |  |
| <del>28</del>  | At least 18 years old, blood type compatible with the donor   | <del>-2500NM</del>   |  |  |  |  |
| <del>29</del>  | Priority 1 and one of the following:  Less than 12 years old and blood type identical to the donor  Less than 1 year old and blood type compatible with the donor  Less than 1 year old and eligible for intended blood group incompatible offers | -Nation  |  |  |  |  |



| Classification | Candidates that are   | And registered at a transplant hospital that is within this distance from the donor hospital |  |  |  |  |
|----------------|---|--|--|--|--|--|
| <del>30</del>  | Priority 1 and one of the following:  At least 1 year old and blood type compatible with the donor  At least 1 year old and eligible for intended blood group incompatible offers | - <del>Nation</del>  |  |  |  |  |
| <del>31</del>  | Priority 2, blood type identical to the donor   |  |  |  |  |  |
| <del>32</del>  | Priority 2, blood type compatible with the donor  | -Nation  |  |  |  |  |
| 33             | 12 to less than 18 years old,<br>blood type identical to the donor  | -Nation  |  |  |  |  |
| <del>3</del> 4 | 12 to less than 18 years old,<br>blood type compatible with the<br>donor  | -Nation  |  |  |  |  |
| 35             | At least 18 years old, blood type identical to the donor  | -Nation  |  |  |  |  |
| <del>36</del>  | At least 18 years old, blood type compatible with the donor   | -Nation  |  |  |  |  |

617

### 10.5 Probability Data Used in the LAS Calculation

Table 10 11: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

| ŧ              | S∓x(t)       | ŧ             | S <sub>TX</sub> (t) | ŧ              | S <sub>TX</sub> (t) | ŧ               | S <sub>TX</sub> (t) | ŧ               | <del>S</del> ∓x <del>(t)</del> |
|----------------|--------------|---------------|---------------------|----------------|---------------------|-----------------|---------------------|-----------------|--------------------------------|
| 0              | 1.0000000000 | 73            | 0.9984903590        | 146            | 0.9975298313        | 219             | 0.9965791846        | 292             | 0.9955475237                   |
| 1              | 0.9999975489 | 74            | 0.9984305838        | 147            | 0.9975146609        | 220             | 0.9965744007        | 293             | 0.9955475237                   |
| 2              | 0.9999827070 | 75            | 0.9984129085        | 148            | 0.9975044749        | <del>221</del>  | 0.9965236975        | <del>29</del> 4 | 0.9955054645                   |
| 3              | 0.9999561442 | 76            | 0.9984027696        | 149            | 0.9974993058        | 222             | 0.9965110962        | 295             | 0.9954978576                   |
| 4              | 0.9999275553 | 77            | 0.9983908074        | <del>150</del> | 0.9974923101        | 223             | 0.9964387358        | <del>296</del>  | 0.9954793243                   |
| 5              | 0.9999018223 | <del>78</del> | 0.9983908074        | <del>151</del> | 0.9974768114        | <del>22</del> 4 | 0.9964387358        | <del>297</del>  | 0.9954639104                   |
| 6              | 0.9998777824 | <del>79</del> | 0.9983787271        | <del>152</del> | 0.9974768114        | 225             | 0.9964227617        | <del>298</del>  | 0.9954392804                   |
| 7              | 0.9998561463 | 80            | 0.9983696472        | 153            | 0.9974554527        | 226             | 0.9964227617        | 299             | 0.9954392804                   |
| 8              | 0.9998143795 | <del>81</del> | 0.9983630336        | <del>154</del> | 0.9974097005        | <del>227</del>  | 0.9964120372        | 300             | 0.9954137179                   |
| 9              | 0.9997863737 | <del>82</del> | 0.9983467929        | <del>155</del> | 0.9973345023        | 228             | 0.9963875823        | <del>301</del>  | 0.9954137179                   |
| 10             | 0.9997696882 | 83            | 0.9983136954        | <del>156</del> | 0.9973345023        | 229             | 0.9963875823        | 302             | 0.9953849510                   |
| 11             | 0.9997397377 | 84            | 0.9983064970        | <del>157</del> | 0.9973270637        | <del>230</del>  | 0.9963684607        | <del>303</del>  | 0.9953581531                   |
| <del>12</del>  | 0.9997045384 | <del>85</del> | 0.9982951177        | <del>158</del> | 0.9973208018        | <del>231</del>  | 0.9963684607        | 304             | 0.9953445180                   |
| 13             | 0.9996823002 | 86            | 0.9982565537        | <del>159</del> | 0.9973148013        | 232             | 0.9963684607        | 305             | 0.9953445180                   |
| <del>1</del> 4 | 0.9996498264 | <del>87</del> | 0.9982441865        | 160            | 0.9972940898        | 233             | 0.9963684607        | 306             | 0.9953445180                   |
| <del>15</del>  | 0.9996353431 | 88            | 0.9982441865        | <del>161</del> | 0.9972940898        | <del>234</del>  | 0.9963684607        | <del>307</del>  | 0.9953093054                   |
| 16             | 0.9996288212 | 89            | 0.9982441865        | <del>162</del> | 0.9972940898        | <del>235</del>  | 0.9963684607        | 308             | 0.9952957037                   |
| 17             | 0.9996154867 | 90            | 0.9982257230        | <del>163</del> | 0.9972727684        | <del>236</del>  | 0.9963684607        | 309             | 0.9952957037                   |
| <del>18</del>  | 0.9995970948 | <del>91</del> | 0.9981791418        | <del>164</del> | 0.9972727684        | <del>237</del>  | 0.9963684607        | <del>310</del>  | 0.9952741113                   |
| <del>19</del>  | 0.9995652300 | <del>92</del> | 0.9981791418        | 165            | 0.9972727684        | 238             | 0.9963684607        | 311             | 0.9952741113                   |

| ŧ             | S <sub>TX</sub> (t) | ŧ   | S <sub>TX</sub> (t) | ŧ   | S <sub>TX</sub> (t) | ŧ   | S <sub>TX</sub> (t) | ŧ              | S <sub>TX</sub> (t) |
|---------------|---------------------|-----|---------------------|-----|---------------------|-----|---------------------|----------------|---------------------|
| 20            | 0.9995271489        | 93  | 0.9981714154        | 166 | 0.9972688422        | 239 | 0.9963684607        | 312            | 0.9952514686        |
| 21            | 0.9995080982        | 94  | 0.9981444359        | 167 | 0.9972234233        | 240 | 0.9963684607        | 313            | 0.9952514686        |
| 22            | 0.9994934457        | 95  | 0.9981313503        | 168 | 0.9972234233        | 241 | 0.9962582929        | 314            | 0.9952514686        |
| 23            | 0.9994602264        | 96  | 0.9981154417        | 169 | 0.9972179105        | 242 | 0.9962582929        | 315            | 0.9952281619        |
| 24            | 0.9994302540        | 97  | 0.9981154417        | 170 | 0.9972086398        | 243 | 0.9961947546        | 316            | 0.9952281619        |
| 25            | 0.9994060375        | 98  | 0.9980759414        | 171 | 0.9972086398        | 244 | 0.9961947546        | 317            | 0.9952281619        |
| 26            | 0.9993816059        | 99  | 0.9980462038        | 172 | 0.9972086398        | 245 | 0.9961947546        | 318            | 0.9951666810        |
| 27            | 0.9993613122        | 100 | 0.9980462038        | 173 | 0.9972086398        | 246 | 0.9960956354        | 319            | 0.9951314001        |
| 28            | 0.9993350553        | 101 | 0.9980357746        | 174 | 0.9972086398        | 247 | 0.9960437794        | 320            | 0.9951314001        |
| 29            | 0.9993022038        | 102 | 0.9980357746        | 175 | 0.9971827158        | 248 | 0.9960247257        | 321            | 0.9951314001        |
| 30            | 0.9992938892        | 103 | 0.9980261747        | 176 | 0.9971692174        | 249 | 0.9959880763        | 322            | 0.9951314001        |
| 31            | 0.9992721423        | 104 | 0.9979909233        | 177 | 0.9971692174        | 250 | 0.9959742895        | 323            | 0.9951314001        |
| 32            | 0.9992622566        | 105 | 0.9979796304        | 178 | 0.9971692174        | 251 | 0.9959742895        | 324            | 0.9950798577        |
| 33            | 0.9992427448        | 106 | 0.9979796304        | 179 | 0.9971692174        | 252 | 0.9959552359        | 325            | 0.9950798577        |
| 34            | 0.9992005080        | 107 | 0.9979760272        | 180 | 0.9971603270        | 253 | 0.9959552359        | 326            | 0.9950798577        |
| 35            | 0.9991776739        | 108 | 0.9979646981        | 181 | 0.9971603270        | 254 | 0.9959380587        | 327            | 0.9950798577        |
| 36            | 0.9991551715        | 109 | 0.9979440109        | 182 | 0.9971320838        | 255 | 0.9959380587        | 328            | 0.9950798577        |
| 37            | 0.9991302006        | 110 | 0.9978768653        | 183 | 0.9971131145        | 256 | 0.9959380587        | 329            | 0.9950798577        |
| 38            | 0.9991278479        | 111 | 0.9978718005        | 184 | 0.9971131145        | 257 | 0.9959380587        | 330            | 0.9950798577        |
| 39            | 0.9991028378        | 112 | 0.9978279771        | 185 | 0.9971091508        | 258 | 0.9959272229        | 331            | 0.9950798577        |
| 40            | 0.9990801777        | 113 | 0.9978239640        | 186 | 0.9970985061        | 259 | 0.9959272229        | 332            | 0.9950670017        |
| 41            | 0.9990600363        | 114 | 0.9978239640        | 187 | 0.9970985061        | 260 | 0.9959225083        | 333            | 0.9949858453        |
| 42            | 0.9990482109        | 115 | 0.9978239640        | 188 | 0.9970985061        | 261 | 0.9959225083        | 334            | 0.9949512121        |
| 43            | 0.9990482109        | 116 | 0.9978239640        | 189 | 0.9970985061        | 262 | 0.9959225083        | 335            | 0.9949512121        |
| 44            | 0.9990358743        | 117 | 0.9978239640        | 190 | 0.9970985061        | 263 | 0.9959225083        | 336            | 0.9949512121        |
| 45            | 0.9990358743        | 118 | 0.9978239640        | 191 | 0.9970985061        | 264 | 0.9959225083        | 337            | 0.9949369873        |
| 46            | 0.9990016655        | 119 | 0.9977825323        | 192 | 0.9970985061        | 265 | 0.9959225083        | 338            | 0.9949369873        |
| 47            | 0.9989778087        | 120 | 0.9977771080        |     |                     | 266 | 0.9958954164        | 339            | 0.9949369873        |
| 48            | 0.9989665684        | 121 | 0.9977674724        | 194 | 0.9970911735        | 267 | 0.9957938685        | 340            | 0.9949369873        |
| 49            | 0.9989492645        | 122 | 0.9977606316        | 195 | 0.9970671621        | 268 | 0.9957938685        | 341            | 0.9949369873        |
| 50            | 0.9989218966        | 123 | 0.9977340449        | 196 | 0.9969683767        | 269 | 0.9957784566        | 342            | 0.9949369873        |
| 51            | 0.9988856853        | 124 | 0.9976558111        | 197 | 0.9969683767        | 270 | 0.9957784566        | 343            | 0.9949369873        |
| 52            | 0.9988518113        | 125 | 0.9976558111        | 198 | 0.9969683767        | 271 | 0.9957784566        | 344            | 0.9948416999        |
| 53            | 0.9988426443        | 126 | 0.9976504510        | 199 | 0.9969587577        | 272 | 0.9957784566        | 345            | 0.9948416999        |
| 54            | 0.9988426443        | 127 | 0.9976370243        | 200 | 0.9969587577        | 273 | 0.9957784566        | 346            | 0.9948416999        |
| 55            | 0.9988209613        | 128 | 0.9976101536        | 201 | 0.9969454938        | 274 | 0.9957702527        | 347            | 0.9947378061        |
| 56            | 0.9988149888        | 129 | 0.9976101536        | 202 | 0.9968612819        | 275 | 0.9957639142        | 348            | 0.9946948263        |
| 57            | 0.9987715012        | 130 | 0.9976101536        | 203 | 0.9968383024        | 276 | 0.9957410244        | 349            | 0.9946845005        |
| 58            | 0.9987338578        | 131 | 0.9975990034        | 204 | 0.9968383024        | 277 | 0.9957255372        | 350            | 0.9946845005        |
| <del>59</del> | 0.9987247079        | 132 | 0.9975835550        | 205 | 0.9968247526        | 278 | 0.9957255372        | 351            | 0.9946845005        |
| 60            | 0.9987034482        | 133 | 0.9975766810        | 206 | 0.9968185781        | 279 | 0.9957255372        | 352            | 0.9946845005        |
| 61            | 0.9987034482        | 134 | 0.9975701094        | 207 | 0.9968185781        | 280 | 0.9957255372        | 353            | 0.9946845005        |
| 62            | 0.9986649209        | 135 | 0.9975701094        | 208 | 0.9968185781        | 281 | 0.9956914479        | 354            | 0.9945854823        |
| 63            | 0.9986649209        | 136 | 0.9975607830        | 209 | 0.9968185781        | 282 | 0.9956914479        | 355            | 0.9945854823        |
| 64            | 0.9986596474        | 137 | 0.9975520103        | 210 | 0.9968097445        | 283 | 0.9956914479        | 356            | 0.9945720480        |
| 65            | 0.9986301115        | 138 | 0.9975404803        | 211 | 0.9967964069        | 284 | 0.9956914479        | 357            | 0.9945265776        |
| 66            | 0.9986166941        | 139 | 0.9975404803        | 212 | 0.9967166260        | 285 | 0.9956797646        | 358            | 0.9945265776        |
| 67            | 0.9985746371        | 140 | 0.9975404803        | 213 | 0.9966358744        | 286 | 0.9956797646        | 359            | 0.9945265776        |
| 68            | 0.9985695968        | 141 | 0.9975404803        | 214 | 0.9966212192        | 287 | 0.9956797646        | 360            | 0.9944766010        |
| <del>69</del> | 0.9985667636        | 142 | 0.9975404803        | 215 | 0.9966212192        | 288 | 0.9956605860        | <del>361</del> | 0.9944766010        |
| 70            | 0.9985563118        | 143 | 0.9975344179        | 216 | 0.9966144147        | 289 | 0.9956605860        | 362            | 0.9944766010        |
| 71            | 0.9985101367        | 144 | 0.9975344179        | 217 | 0.9966016656        | 290 | 0.9956391439        | 363            | 0.9944766010        |
| 72            | 0.9984938912        | 145 | 0.9975344179        | 218 | 0.9965791846        | 291 | 0.9956391439        | 364            | 0.9943896539        |
|               | 3.555.556512        |     | 3.55.55111.5        |     | 3.33337,31010       |     | 3.5555551155        |                | 3.55 .5555555       |

618



Table 10-12: Baseline Post-Transplant Survival (S<sub>TX</sub>(t)) Probability Where t=Time in Days

|               |                         |                |                         |                | (-1/(-7/                |                | .,                      |                 | ,                       |
|---------------|-------------------------|----------------|-------------------------|----------------|-------------------------|----------------|-------------------------|-----------------|-------------------------|
| ŧ             | S <sub>TX</sub> (t)     | ŧ              | S <sub>IX</sub> (t)     | ŧ              | S <sub>IX</sub> (t)     | ŧ              | S <sub>IX</sub> (t)     | ŧ               | S <sub>IX</sub> (t)     |
| 0             | 1.0000000000            | 73             | 0.9821718893            | 146            | 0.9760705488            | 219            | 0.9685147964            | 292             | 0.9612475822            |
| 1             | 0.9989168684            | 74             | 0.9821718893            | 147            | 0.9760079584            | 220            | 0.9684514491            | 293             | 0.9611192441            |
| 2             | 0.9984346294            | 75             | 0.9821718893            | 148            | 0.9759453602            | 221            | 0.9683880937            | <del>29</del> 4 | 0.9609908927            |
| 3             | 0.9977712423            | 76             | 0.9821099189            | 149            | 0.9758201487            | 222            | 0.9682613699            | 295             | 0.9609908927            |
| 4             | 0.9973484709            | 77             | 0.9820479459            | 150            | 0.9757575320            | 223            | 0.9681979935            | 296             | 0.9607341600            |
| 5             | 0.9970462337            | 78             | 0.9819859697            | <del>151</del> | 0.9757575320            | 224            | 0.9681346105            | <del>297</del>  | 0.9606699547            |
| 6             | 0.9965625190            | <del>79</del>  | 0.9819239837            | <del>152</del> | 0.9754444350            | 225            | 0.9681346105            | 298             | 0.9605415356            |
| 7             | 0.9961993881            | 80             | 0.9818000096            | 153            | 0.9753817621            | 226            | 0.9681346105            | 299             | 0.9604130979            |
| 8             | 0.9958966278            | 81             | 0.9818000096            | 154            | 0.9752564117            | 227            | 0.9678810937            | 300             | 0.9604130979            |
| 9             | 0.9954724846            | 82             | 0.9817380113            | 155            | 0.9751937214            | 228            | 0.9678810937            | 301             | 0.9604130979            |
| 10            | 0.9951086930            | 83             | 0.9816760095            | 156            | 0.9751310267            | 229            | 0.9676274650            | 302             | 0.9602846512            |
| 11            | 0.9948053130            | 84             | 0.9816760095            | 157            | 0.9750683237            | 230            | 0.9675640123            | 303             | 0.9602204141            |
| 12            | 0.9942589911            | 85             | 0.9816140030            | 158            | 0.9748802003            | 231            | 0.9675005516            | 304             | 0.9600277027            |
| 13            | 0.9941374518            | 86             | 0.9814899878            | 159            | 0.9748174678            | 232            | 0.9675005516            | 305             | 0.9599634408            |
| 14            | 0.9938943616            | 87             | 0.9813659495            | 160            | 0.9747547321            | 233            | 0.9675005516            | 306             | 0.9599634408            |
|               |                         |                |                         |                |                         |                |                         |                 |                         |
| 15<br>16      | 0.9936511061            | 88             | 0.9812418882            | 161<br>162     | 0.9746919892            | 234            | 0.9669292385            | 307             | 0.9598349128            |
| 16            | 0.9932859829            | 89             | 0.9811178010            | 162            | 0.9746292392            | 235            |                         | 308             | 0.9596420886            |
| 17            | 0.9931032767            | 90             | 0.9811178010            | 163            | 0.9745037272            | 236            | 0.9667386173            | 309             | 0.9595777902            |
| 18            | 0.9927987155            | 91             | 0.9809936908            | 164            | 0.9744409567            | 237            | 0.9666114980            | 310             | 0.9594491836            |
| <del>19</del> | 0.9925549731            | 92             | 0.9809936908            | 165            | 0.9743154118            | 238            | 0.9664843455            | 311             | 0.9593205637            |
| 20            | 0.9924330443            | 93             | 0.9809936908            | 166            | 0.9741898451            | 239            | 0.9664843455            | 312             | 0.9591919322            |
| 21            | 0.9921891249            | 94             | 0.9808074944            | <del>167</del> | 0.9741270468            | <del>240</del> | 0.9664207511            | 313             | 0.9590632846            |
| 22            | 0.9920061484            | 95             | 0.9808074944            | <del>168</del> | 0.9741270468            | <del>241</del> | 0.9663571531            | 314             | 0.9589346060            |
| 23            | 0.9916401290            | 96             | <del>0.9806833301</del> | <del>169</del> | <del>0.9740014458</del> | 242            | <del>0.9661663551</del> | <del>315</del>  | <del>0.9588059096</del> |
| <del>24</del> | <del>0.9914570116</del> | <del>97</del>  | 0.9804970537            | <del>170</del> | 0.9738758131            | 243            | 0.9660391221            | <del>316</del>  | <del>0.9587415497</del> |
| <del>25</del> | 0.9913959504            | 98             | 0.9804349392            | <del>171</del> | <del>0.9738758131</del> | 244            | 0.9659118728            | <del>317</del>  | <del>0.9586128181</del> |
| <del>26</del> | 0.9910906393            | 99             | <del>0.9801864682</del> | <del>172</del> | <del>0.9736245232</del> | <del>245</del> | 0.9659118728            | <del>318</del>  | <del>0.9585484383</del> |
| <del>27</del> | 0.9909073743            | 100            | 0.9800000394            | <del>173</del> | <del>0.9735616621</del> | <del>246</del> | 0.9657209456            | <del>319</del>  | 0.9585484383            |
| 28            | 0.9904797245            | 101            | 0.9799378767            | <del>174</del> | 0.9734359312            | <del>247</del> | 0.9657209456            | 320             | 0.9584840545            |
| <del>29</del> | 0.9899294478            | 102            | 0.9798135405            | 175            | 0.9733101762            | 248            | 0.9655936296            | <del>321</del>  | 0.9584196607            |
| 30            | 0.9898070359            | 103            | 0.9796891562            | <del>176</del> | 0.9732472868            | 249            | 0.9655299608            | 322             | 0.9582908711            |
| 31            | 0.9891950158            | 104            | 0.9796891562            | <del>177</del> | 0.9729957417            | 250            | 0.9655299608            | 323             | 0.9582908711            |
| <del>32</del> | 0.9887660579            | 105            | 0.9796891562            | 178            | 0.9729957417            | 251            | 0.9654662741            | 324             | 0.9580976632            |
| 33            | 0.9886434002            | <del>106</del> | 0.9796269487            | <del>179</del> | 179 0.9729328284        |                | 0.9654662741            | 325             | 0.9579688088            |
| 34            | 0.9884593786            | 107            | 0.9794403086            | 180            | 0.9728069960            | 253            | 0.9652115383            | 326             | 0.9579688088            |
| 35            | 0.9880912671            | 108            | 0.9793780730            | 181            | 0.9728069960            | 254            | 0.9650840942            | 327             | 0.9579043700            |
| 36            | 0.9879070815            | 109            | 0.9793158337            | 182            | 0.9724923862            | 255            | 0.9648928664            | 328             | 0.9577754767            |
| 37            | 0.9877842742            | 110            | 0.9792535831            | 183            | 0.9724923862            | 256            | 0.9647015529            | 329             | 0.9577754767            |
| 38            | 0.9873544476            | 111            | 0.9792535831            | 184            | 0.9723664833            | 257            | 0.9646377632            | 330             | 0.9577110163            |
| 39            | 0.9871700789            | 112            | 0.9791290692            | 185            | 0.9723035158            | 258            | 0.9645739650            | 331             | 0.9576465538            |
| 40            | 0.9869242045            | 113            | 0.9790668010            | 186            | 0.9721146241            | 259            | 0.9645101605            | 332             | 0.9574531426            |
| 41            | 0.9869242045            | 114            | 0.9788176541            | 187            | 0.9720516381            | 260            | 0.9643187339            | 333             | 0.9572596959            |
| 42            | 0.9868627089            | 115            | 0.9787553419            | 188            | 0.9719256562            | <del>261</del> | 0.9642548867            | 334             | 0.9569371935            |
| 43            | 0.9866167108            | 116            | 0.9786930245            | 189            | 0.9716736755            | 262            | 0.9641910389            | 335             | 0.9566145449            |
| 44            | 0.9865551891            | 117            | 0.9786307023            | 190            | 0.9715476030            | 263            | 0.9640633401            | 336             | 0.9564208317            |
| 45            |                         | 118            |                         | 191            |                         | <del>264</del> |                         | 337             |                         |
| _             | 0.9864321394            | <b>-</b>       | 0.9785060459            |                | 0.9712954163            |                | 0.9638717349            |                 | 0.9561624675            |
| 46            | 0.9863705962            | 119            | 0.9785060459            | 192            | 0.9712323468            | 265            | 0.9638078451            | 338             | 0.9560332045            |
| 47            | 0.9861243805            | 120            | 0.9783190327            | 193            | 0.9711692727            | 266            | 0.9636800525            | 339             | 0.9559039159            |
| 48            | 0.9859396692            | 121            | 0.9782566683            | 194            | 0.9711061937            | 267            | 0.9635522259            | 340             | 0.9556453115            |
| 49            | 0.9859396692            | 122            | 0.9781942967            | 195            | 0.9711061937            | 268            | 0.9634883010            | 341             | 0.9555806338            |
| <del>50</del> | 0.9858164949            | 123            | 0.9781319182            | 196            | 0.9711061937            | 269            | 0.9632965280            | 342             | 0.9555806338            |
| 51            | 0.9855701194            | <del>124</del> | 0.9779447835            | 197            | 0.9708538746            | 270            | 0.9631686533            | 343             | 0.9555159535            |
| <del>52</del> | 0.9855701194            | <del>125</del> | 0.9779447835            | <del>198</del> | 0.9706645555            | <del>271</del> | 0.9631686533            | 344             | 0.9554512674            |
| <del>53</del> | 0.9853236329            | <del>126</del> | <del>0.9778200018</del> | 199            | <del>0.9705383076</del> | <del>272</del> | 0.9631686533            | 345             | 0.9553865754            |
| 54            | 0.9850154170            | <del>127</del> | <del>0.9777575984</del> | 200            | 0.9703489195            | <del>273</del> | 0.9631686533            | <del>346</del>  | 0.9553865754            |
| 55            | 0.9847070827            | <del>128</del> | <del>0.9777575984</del> | <del>201</del> | 0.9702226203            | <del>274</del> | 0.9629768044            | 347             | 0.9553218775            |
| <del>56</del> | <del>0.9846453556</del> | <del>129</del> | 0.9777575984            | <del>202</del> | 0.9700962568            | <del>275</del> | <del>0.9629128396</del> | 348             | 0.9552571738            |
|               |                         |                |                         |                |                         |                |                         |                 |                         |



| ŧ             | S <sub>TX</sub> (t) | ŧ               | S <sub>TX</sub> (t) | ŧ              | S <sub>TX</sub> (t)     | ŧ               | S <sub>TX</sub> (t) | ŧ              | S <sub>TX</sub> (t) |
|---------------|---------------------|-----------------|---------------------|----------------|-------------------------|-----------------|---------------------|----------------|---------------------|
| <del>57</del> | 0.9844601577        | <del>130</del>  | 0.9777575984        | <del>203</del> | 0.9699066925            | <del>276</del>  | 0.9628488713        | <del>349</del> | 0.9550630638        |
| 58            | 0.9842749162        | 131             | 0.9776951904        | 204            | 0.9698434819            | 277             | 0.9627209262        | 350            | 0.9550630638        |
| <del>59</del> | 0.9841513879        | <del>132</del>  | 0.9775703575        | <del>205</del> | 0.9698434819            | <del>278</del>  | 0.9627209262        | <del>351</del> | 0.9548041910        |
| 60            | 0.9838425267        | <del>133</del>  | 0.9775703575        | <del>206</del> | 0.9697802663            | <del>279</del>  | 0.9625929760        | <del>352</del> | 0.9546099416        |
| 61            | 0.9837807200        | <del>13</del> 4 | 0.9775703575        | <del>207</del> | 0.9694642073            | 280             | 0.9625929760        | 353            | 0.9544803563        |
| 62            | 0.9835952969        | 135             | 0.9775079236        | 208            | 0.9693376951            | 281             | 0.9625289763        | 354            | 0.9544803563        |
| 63            | 0.9835334714        | <del>136</del>  | 0.9772581879        | 209            | 0.9692111628            | 282             | 0.9623369773        | 355            | 0.9544155483        |
| 64            | 0.9834716335        | <del>137</del>  | 0.9771332758        | 210            | 0.9691478845            | <del>283</del>  | 0.9623369773        | <del>356</del> | 0.9542211322        |
| 65            | 0.9832242857        | 138             | 0.9771332758        | 211            | 0.9691478845            | <del>28</del> 4 | 0.9623369773        | 357            | 0.9539618458        |
| 66            | 0.9831624223        | <del>139</del>  | 0.9769458756        | <del>212</del> | 0.9691478845            | 285             | 0.9621448872        | 358            | 0.9538321500        |
| <del>67</del> | 0.9831624223        | 140             | 0.9767584228        | 213            | 0.9690213151            | <del>286</del>  | 0.9618886886        | <del>359</del> | 0.9537024130        |
| 68            | 0.9830386904        | 141             | 0.9766959165        | 214            | 0.9688947255            | <del>287</del>  | 0.9617605348        | 360            | 0.9535077925        |
| 69            | 0.9827292921        | 142             | 0.9766959165        | 215            | <del>0.9687681067</del> | 288             | 0.9617605348        | <del>361</del> | 0.9535077925        |
| 70            | 0.9824197258        | 143             | 0.9765708928        | <del>216</del> | 0.9687681067            | <del>289</del>  | 0.9616964401        | <del>362</del> | 0.9535077925        |
| 71            | 0.9823577717        | 144             | 0.9763207692        | 217            | 0.9687681067            | <del>290</del>  | 0.9614400217        | <del>363</del> | 0.9535077925        |
| <del>72</del> | 0.9822338558        | 145             | 0.9763207692        | 218            | 0.9686414652            | <del>291</del>  | 0.9614400217        | 364            | 0.9535077925        |

### Policy 10: Allocation of Lungs

### 10.1 Lung Composite Allocation Score

- The lung composite allocation score is the combined total of the candidate's lung medical urgency score,
- 625 lung post-transplant outcomes score, lung biological disadvantages score, lung patient access score and
- lung efficiency score. The lung composite allocation score is awarded on a scale from 0 to 100.

627 628

629

623

Candidates will be rank-ordered by lung composite allocation score. If two or more candidates have the same lung composite allocation score, the tied candidates will be ranked by order of their registration date (oldest to newest).

630 631 632

#### **10.1.A Prioritizing Medically Urgent Candidates**

The lung medical urgency score is equal to the candidate's lung waitlist survival points.

633634635

636

637

638

639 640

641

642

643 644

645

646

647

648

649 650

651 652

653 654

655

656 657

658

659

660

661

#### 10.1.A.1. Waitlist Survival Points for Candidates at least 12 Years Old

For candidates at least 12 years old at the time of the match lung waitlist survival points awarded based on the candidate's waiting list survival probability, based on the following factors:

- Age at the time of the match (fractional calendar years)
- Bilirubin (mg/dL) value with the most recent test date and time
- Body mass index (BMI) (kg/m2)
- Ventilation status if candidate is hospitalized
- Creatinine (serum) (mg/dL) with the most recent test date and time
- Diagnosis Group (A, B, C, or D), as defined in [x-ref]
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group A:
  - o Bronchiectasis
  - Sarcoidosis with PA mean pressure of 30 mm Hg or less
- Whether the candidate has one of the following specific diagnoses within Diagnosis Group D:
  - Pulmonary fibrosis, other specify cause
  - o Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Functional Status
- Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)
- PCO2 (mm Hg): current
- PCO2 increase of at least 15%
- Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise
- Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.

Lung waitlist survival points are awarded on a scale of 0-25. *Policy 21.1.A: Waiting List Survival Formulas* details the calculation of lung waitlist survival points.

| 565 | 10.1.A.2 Waitlist Survival Points for Candidates Less than 12 Years Old   |
|-----|---|
| 566 | Lung candidates assigned pediatric priority 1 receive 1.90727062 waitlist survival points based                     |
| 667 | on the candidate's waitlist survival probability.   |
| 668 | Lung candidates less than 12 years old assigned pediatric priority 2 receive 0.4406045375                           |
| 669 | waitlist survival points based on the candidate's waitlist survival probability.                                    |
| 570 | <del></del>   |
| 571 | 10.1.A.2.a Candidates Less than 12 Years Old - Priority 1   |
| 572 | A lung candidate less than 12 years old may be assigned priority 1 if at least one of the following                 |
| 573 | requirements is met:  |
| 574 |   |
| 575 | 1. Candidate has respiratory failure, evidenced by at least one of the following:                                   |
| 576 | Requires continuous mechanical ventilation  |
| 577 | <ul> <li>Requires supplemental oxygen delivered by any means to achieve FiO<sub>2</sub> greater than 50%</li> </ul> |
| 578 | in order to maintain oxygen saturation levels greater than 90%  |
| 579 | Has an arterial or capillary PCO <sub>2</sub> greater than 50 mm Hg   |
| 580 | <ul> <li>Has a venous PCO<sub>2</sub> greater than 56 mm Hg</li> </ul>  |
| 581 |   |
| 582 | 2. Pulmonary hypertension, evidenced by at least one of the following:  |
| 583 | <ul> <li>Has pulmonary vein stenosis involving 3 or more vessels</li> </ul>   |
| 584 | <ul> <li>Exhibits any of the following, in spite of medical therapy:</li> </ul>                                     |
| 585 | o Cardiac index less than 2 L/min/M <sup>2</sup>  |
| 586 | o Syncope   |
| 587 | o <u>Hemoptysis</u>   |
| 588 | <ul> <li>Suprasystemic PA pressure on cardiac catheterization or by echocardiogram</li> </ul>                       |
| 589 | <u>estimate</u>   |
| 590 |   |
| 591 | The OPTN will maintain examples of accepted medical therapy for pulmonary hypertension.                             |
| 592 | Transplant programs must indicate which of these medical therapies the candidate has received.                      |
| 593 |   |
| 594 | 10.1.A.2.b Candidates Less than 12 Years Old - Priority 2   |
| 595 | If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for                   |
| 596 | priority level 1, then the candidate is assigned priority 2.  |
| 597 |   |
| 598 | 10.1.B Improving Post Transplant Outcomes   |
| 599 | Each lung candidate is assigned a lung post-transplant outcomes score. The lung post-transplant                     |
| 700 | outcomes score is equal to the candidate's lung post-transplant outcomes points.                                    |
| 701 |   |
| 702 | 10.1.B.1 Post Transplant Outcomes Points for Candidates at Least 12 Years Old                                       |
| 703 | For candidates at least 12 years old at the time of the match, lung post-transplant outcomes                        |
| 704 | points are awarded based on the candidate's waiting list survival probability, based on the                         |
| 705 | following factors:  |
| 706 | <ul> <li>Age at the time of the match (portion of years, calculated daily)</li> </ul>                               |
| 707 | • Creatining (serum) (mg/dl) with the most recent data and time   |

| 708 | <ul> <li>Cardiac index (L/min/m2) at rest, prior to any exercise</li> </ul>                               |
|-----|---|
| 709 | <ul> <li>Ventilation status if candidate is hospitalized</li> </ul>                                       |
| 710 | <ul> <li>Diagnosis Group (A, B, C, or D), as defined in [x-ref]</li> </ul>                                |
| 711 | <ul> <li>Whether the candidate has one of the following specific diagnoses within Diagnosis</li> </ul>    |
| 712 | Group A:  |
| 713 | o <u>Bronchiectasis</u>   |
| 714 | <ul> <li>Sarcoidosis with PA mean pressure of 30 mm Hg or less</li> </ul>                                 |
| 715 | <ul> <li>Whether the candidate has one of the following specific diagnoses within Diagnosis</li> </ul>    |
| 716 | Group D:  |
| 717 | <ul> <li>Obliterative bronchiolitis (not-retransplant)</li> </ul>   |
| 718 | <ul> <li>Sarcoidosis with PA mean pressure greater than 30 mm Hg</li> </ul>                               |
| 719 | Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)                     |
| 720 | Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental                        |
| 721 | oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in                   |
| 722 | supplemental oxygen during this test is at the discretion of the center performing the                    |
| 723 | test  |
| 724 | Lung post-transplant outcomes points are awarded on a scale of 0-25. Policy 21.1.B: Post-                 |
| 725 | Transplant Outcomes Formulas details the calculation of lung post-transplant outcomes points.             |
| 726 |   |
| 727 | 10.1.B.2 Post-Transplant Outcomes Points for Candidates Less than 12 years Old                            |
| 728 | Lung candidates who are less than 12 years old are assigned 18.63362541 post-transplant                   |
| 729 | outcomes points based on the candidate's waiting list survival probability.                               |
| 730 |   |
| 731 | 10.1.C Reducing Biological Disadvantages  |
| /31 | 10.1.e Reducing Diological Disadvantages  |
| 732 | Each lung candidate is assigned a lung biological disadvantages score. The lung biological disadvantages  |
| 733 | score is equal to the total of the candidate's lung ABO points, lung CPRA points, and lung height points. |
| 734 |   |
| 735 | 10.1.C.1 Allocation of Lungs by Blood Type  |
| 736 | Each lung candidate is assigned lung ABO points determined based on the proportion of donors              |
| 737 | the candidate could accept based on blood type compatibility, according to Table 1: ABO Points            |
| 738 | by Blood Type. Candidates who are eligible to accept blood group incompatible donors                      |
| 739 | according to Policy 10.4.A Eligibility for Intended Blood Group Incompatible Offers for Deceased          |
| 740 | Donor Lungs receive the same ABO points as other candidates in their blood group.                         |
| 741 |   |
| 742 | Table 10-1: ABO Points by Blood Type  |

#### Table 10-1: ABO Points by Blood Type

| A candidate with a blood type of | Will receive this many lung ABO |
|----------------------------------|---------------------------------|
|                                  | <u>points</u>                   |
| <u>AB</u>                        | <u>0</u>                        |
| <u>A</u>                         | <u>.0455468628</u>              |
| <u>B</u>                         | <u>.2438521158</u>              |
| <u>O</u>                         | <u>.45496835845</u>             |

743

| 744                             | 10.1.C.2 CPRA  |
|---------------------------------|--|
| 745<br>746<br>747<br>748        | Each lung candidate is assigned lung CPRA points based on the proportion of donors the candidate could accept based on antigen acceptability. Lung CPRA points are awarded on a scale of 0-5. <i>Policy 21.1.C.1: Lung CPRA Points</i> details the calculation of lung CPRA points.  |
| 749                             | 10.1.C.3 Height  |
| 750<br>751<br>752<br>753        | Each lung candidate is assigned lung height points based on the proportion of donors the candidate could accept based on height compatibility. Lung height points are awarded on a scale of 0-5. <i>Policy 21.2.C.1: Lung Height Points</i> details the calculation of lung height points.   |
| 754                             | 10.1.D Promoting Patient Access  |
| 755<br>756<br>757               | The lung patient access score is equal to the total of the candidate's lung pediatric points and lung living donor points.   |
| 758                             | 10.1.D.1 Pediatric Candidates  |
| 759<br>760<br>761               | A candidate who was less than 18 years old at the time of registration on the lung waiting list will receive 20 lung pediatric points.   |
| 762                             | 10.1.D.2 Prior Living Donors   |
| 763<br>764                      | A candidate who is a prior living organ donor will receive 5 lung living donor points.   |
| 765                             | 10.1.E Promoting the Efficient Management of the Organ Placement System  |
| 766<br>767<br>768               | The lung efficiency score is the total of the candidate's lung travel efficiency and lung proximity efficiency points.   |
| 769                             | 10.1.E.1 Travel Efficiency   |
| 770<br>771<br>772<br>773<br>774 | A candidate's lung travel efficiency points are determined based on the straight line distance between the donor hospital and the transplant hospitals where the candidate is listed. Lung travel efficiency points are awarded on a scale of 0-5. Policy 21.1.D.1: Lung Travel Efficiency Points details the calculation of lung travel efficiency points.          |
| 775                             | 10.1.E.2 Proximity Efficiency  |
| 776<br>777<br>778<br>779<br>780 | A candidate's lung proximity efficiency points are determined based on the straight line distance between the donor hospital and the transplant hospitals where the candidate is listed. Lung proximity efficiency points are awarded on a scale of 0-5. Policy 21.1.D.2: Lung Proximity Efficiency Points details the calculation of lung travel efficiency points. |
| 781                             | 10.1.F Lung Disease Diagnosis Groups   |
| 782<br>783<br>784               | Each candidate is assigned a diagnosis group, based on their lung disease diagnosis, which is used in the calculation of their medical urgency score and their post-transplant survival score.   |

Group A

785

| 786<br>787 | A candidate is in Group A if the candidate has any of the following diagnoses:        |
|------------|---|
| 787<br>788 | Allergic bronchopulmonary aspergillosis   |
| 789        | Alpha-1 antitrypsin deficiency  |
| 790        | Bronchiectasis  |
| 791        | Bronchopulmonary dysplasia  |
| 792        | Chronic obstructive pulmonary disease/emphysema                                       |
| 793        | Ehlers-Danlos syndrome  |
| 794        | Granulomatous lung disease  |
| 795        | Inhalation burns/trauma   |
| 796        | Kartagener's syndrome   |
| 797        | Lymphangioleiomyomatosis  |
| 798        | Obstructive lung disease  |
| 799        | Primary ciliary dyskinesia;   |
| 800        | Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less                   |
| 801        | Tuberous sclerosis  |
| 802        | Wegener's granuloma – bronchiectasis  |
| 803        | - Transmit Stonemeotasis  |
| 804        | Group B   |
| 805        | A candidate is in Group B if the candidate has any of the following diagnoses:        |
| 806        |   |
| 807        | Congenital malformation   |
| 808        | CREST – pulmonary hypertension  |
| 809        | Eisenmenger's syndrome: atrial septal defect (ASD)                                    |
| 810        | Eisenmenger's syndrome: multi-congenital anomalies                                    |
| 811        | • Eisenmenger's syndrome: other specify   |
| 812        | Eisenmenger's syndrome: patent ductus arteriosus (PDA)                                |
| 813        | • Eisenmenger's syndrome: ventricular septal defect (VSD)                             |
| 814        | Portopulmonary hypertension   |
| 815        | <ul> <li>Primary pulmonary hypertension/pulmonary arterial hypertension</li> </ul>    |
| 816        | Pulmonary capillary hemangiomatosis   |
| 817        | <ul> <li><u>Pulmonary telangiectasia – pulmonary hypertension</u></li> </ul>          |
| 818        | <ul> <li>Pulmonary thromboembolic disease</li> </ul>                                  |
| 819        | Pulmonary vascular disease  |
| 820        | <ul> <li>Pulmonary veno-occlusive disease</li> </ul>                                  |
| 821        | <ul> <li>Pulmonic stenosis</li> </ul>   |
| 822        | Right hypoplastic lung  |
| 823        | <ul> <li>Scleroderma – pulmonary hypertension</li> </ul>                              |
| 824        | <ul> <li>Secondary pulmonary hypertension</li> </ul>                                  |
| 825        | <ul> <li><u>Thromboembolic pulmonary hypertension</u></li> </ul>                      |
| 826        |   |
| 827        | Group C   |
| 828<br>829 | A candidate is in Group C if the candidate has <i>any</i> of the following diagnoses: |
| 830        | Common variable immune deficiency   |

| 831 | •          | Cystic fibrosis   |
|-----|------------|---|
| 832 |            | Fibrocavitary lung disease  |
| 833 | •          | ·   |
| 834 | •          | Hypogammaglobulinemia Schwarbman Diamond syndrome   |
|     | •          | Schwachman-Diamond syndrome   |
| 835 | C.,        | our D   |
| 836 |            | oup D   |
| 837 | <u>A C</u> | candidate is in Group D if the candidate has any of the following diagnoses:                    |
| 838 |            | ADCA2 transport an acceptable a   |
| 839 | •          | About a section as in a size  |
| 840 | •          | Alveolar proteinosis  |
| 841 | •          | <u>Amyloidosis</u>  |
| 842 | •          | Acute respiratory distress syndrome or pneumonia  |
| 843 | •          | Bronchioloalveolar carcinoma (BAC)  |
| 844 | •          | <u>Carcinoid tumorlets</u>  |
| 845 | •          | Chronic pneumonitis of infancy  |
| 846 | •          | Constrictive bronchiolitis  |
| 847 | •          | COVID-19: acute respiratory distress syndrome   |
| 848 | •          | COVID-19: pulmonary fibrosis  |
| 849 | •          | <u>CREST – Restrictive</u>  |
| 850 | •          | Eosinophilic granuloma  |
| 851 | •          | Fibrosing Mediastinitis   |
| 852 | •          | Graft versus host disease (GVHD)  |
| 853 | •          | <u>Hermansky Pudlak syndrome</u>  |
| 854 | •          | Hypersensitivity pneumonitis  |
| 855 | •          | Idiopathic interstitial pneumonia, with at least one or more of the following disease entities: |
| 856 |            | o Acute interstitial pneumonia  |
| 857 |            | o Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)    |
| 858 |            | <ul> <li>Desquamative interstitial pneumonia</li> </ul>   |
| 859 |            | o <u>Idiopathic pulmonary fibrosis (IPF)</u>  |
| 860 |            | <ul> <li>Nonspecific interstitial pneumonia</li> </ul>  |
| 861 |            | <ul> <li>Lymphocytic interstitial pneumonia (LIP)</li> </ul>                                    |
| 862 |            | <ul> <li>Respiratory bronchiolitis-associated interstitial lung disease</li> </ul>              |
| 863 | •          | Idiopathic pulmonary hemosiderosis  |
| 864 | •          | Lung retransplant or graft failure: acute rejection   |
| 865 | •          | Lung retransplant or graft failure: non-specific  |
| 866 | •          | Lung retransplant or graft failure: obliterative bronchiolitis-obstructive                      |
| 867 | •          | Lung retransplant or graft failure: obliterative bronchiolitis-restrictive                      |
| 868 | •          | Lung retransplant or graft failure: obstructive   |
| 869 | •          | Lung retransplant or graft failure: other specify   |
| 870 | •          | Lung retransplant or graft failure: primary graft failure                                       |
| 871 | •          | Lung retransplant or graft failure: restrictive   |
| 872 | •          | <u>Lupus</u>  |
| 873 | •          | Mixed connective tissue disease   |
| 874 | •          | Obliterative bronchiolitis: non-retransplant  |
| 875 | •          | Occupational lung disease: other specify  |
| 876 | •          | Paraneoplastic pemphigus associated Castleman's disease   |

921

| 877        | • Polymyositis   |
|------------|--|
| 878        | <ul> <li>Pulmonary fibrosis: other specify cause</li> </ul>  |
| 879        | Pulmonary hyalinizing granuloma  |
| 880        | <ul> <li>Pulmonary lymphangiectasia (PL)</li> </ul>  |
| 881        | Pulmonary telangiectasia – restrictive   |
| 882        | Rheumatoid disease   |
| 883        | Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg   |
| 884        | Scleroderma – restrictive  |
| 885        | Secondary pulmonary fibrosis: (specify cause)  |
| 886        | • Silicosis  |
| 887        | Sjogren's syndrome   |
| 888        | Surfactant protein B mutation  |
| 889        | Surfactant protein C mutation  |
| 890        | Teratoma   |
| 891        | Wegener's granuloma – restrictive  |
| 892        | <u></u>  |
| 893        | 10.2 Lung Composite Score Exceptions   |
|            |  |
| 894        | If a candidate's current lung composite allocation score does not appropriately prioritize the candidate   |
| 895        | for transplant, the candidate's transplant program may submit an exception request to the Review   |
| 896<br>897 | Board. A candidate's lung composite allocation score cannot exceed 100, inclusive of score exceptions.   |
| 898        | 10.2.A Review Board Composition  |
| 090        | 10.2.A Review Board Composition  |
| 899        | For lung exceptions, there is a lung review board.   |
| 900        |  |
| 901        | The lung review board reviews lung medical urgency score, lung post-transplant outcomes  |
| 902        | score, lung biological disadvantages score, lung patient access score, and lung efficiency score   |
| 903        | exceptions. Its membership will be comprised of nine physicians and surgeons from approved   |
| 904        | lung programs and their alternates. At least three will be from lung programs with approved  |
| 905        | pediatric programs.  |
| 906        | The Lung Transplantation Committee will develop and approve enerational guidelines that detail   |
| 907        | The Lung Transplantation Committee will develop and approve operational guidelines that detail the administrative details of the review board operations. The Lung Transplantation Committee |
| 908<br>909 | may develop clinical guidance documents for specific clinical scenarios. These guidelines may  |
| 910        | include appropriate documentation for the review board to consider, appropriate clinical values  |
| 911        | and suggested (but not automatically accepted) exception requests.   |
| 912        | and suggested (but not automatically accepted) exception requests.   |
| 913        | 10.2.B Exception Requests  |
| 914        | An exception request must include all of the following:  |
| 915        | Indication of one or more applicable goals in the composite allocation score   |
| 916        | A request for a specific score   |
| 917        | 3. A justification of how the medical criteria supports the higher score for the candidate   |
| 918        | 4. An explanation of how the candidate's current condition is comparable to that of other  |
| 919        | candidates with the requested score  |
| 920        | Approved exception scores are valid until the candidate is transplanted, is removed from the   |
|            |  |

104 Public Comment Proposal

lung waiting list, or withdraws the exception.

| 922        |   |
|------------|---|
| 923        | 10.2.C Review of Exceptions   |
| 924        | The review board must review exception or extension requests within five days of the date the             |
| 925        | request is submitted to the review board. If the Review Board fails to make a decision on the             |
| 926        | initial exception or extension request by the end of the five day review period, the candidate will       |
| 927        | be assigned the requested exception score.  |
| 928        | be assigned the requested exception score.  |
| 929        | 10.2.D Appeals to Lung Review Board   |
| 020        | If the Lung Deview Deard denies an exception or extension request the condidate's transplant              |
| 930        | If the Lung Review Board denies an exception or extension request, the candidate's transplant             |
| 931        | program may appeal to the Lung Review Board within seven days of receiving the denial. The                |
| 932        | Lung Review Board must review appeals within five days of the date the appeal is submitted to             |
| 933        | the OPTN. If the Lung Review Board fails to make a decision on the appeal by the end of the five          |
| 934        | day appeal period or fails to reach quorum, the candidate will be assigned the requested                  |
| 935        | exception score.  |
| 936<br>937 | 10.2.E Appeals to Lung Transplantation Committee  |
| 020        | If the Loren Devices Decod device an escention an estention required to a consel the condidate/           |
| 938        | If the Lung Review Board denies an exception or extension request on appeal, the candidate's              |
| 939        | transplant program may appeal to the Lung Transplantation Committee within fourteen days of               |
| 940        | receiving the denial. The Lung Transplantation Committee must review appeals at its next                  |
| 941<br>942 | scheduled meeting.  |
|            |   |
| 943        | .0.3 Clinical Update Schedule   |
| 944        |   |
| 945        | 10.3.A Lung Clinical Values That Must Be Updated Every 28 Days  |
| 946        | A transplant hospital must update all of the following clinical values at least once in every 28 day      |
| 947        | period after the transplant hospital reports that a candidate on the lung waiting list is on              |
| 948        | continuous mechanical ventilation or ECMO, or requires supplemental oxygen provided via a                 |
| 949        | high flow oxygen device:  |
| 950        | Supplemental oxygen requirements to maintain adequate oxygen saturation (88% or saturation)               |
| 951        | greater) at rest (L/min)  |
| 952        | <ul> <li>Assisted ventilation status</li> </ul>   |
| 953        |   |
| 954        | 10.3.B Lung Clinical Values That Must Be Updated Every Six Months   |
| 955        | Transplant hospitals must update all of the following clinical values at least once in every six          |
| 956        | month period following registration for each candidate on the lung waiting list:                          |
| 957        | Bilirubin (mg/dL) value with the most recent test date and time   |
| 958        | Body mass index (BMI) (kg/m2)   |
| 959        | Creatinine (serum) (mg/dL) value with the most recent test date and time                                  |
| 960        | Functional Status   |
| 961        | <ul> <li>Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)</li> </ul> |
| 962        | PCO <sub>2</sub> (mm Hg)  |
|            | · 5 1   |

| 963 | • Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental              |
|-----|---|
| 964 | oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in               |
| 965 | supplemental oxygen during this test is at the discretion of the center performing the                |
| 966 | test.   |
| 967 | Ventilation status if candidate is hospitalized   |
| 968 | The transplant program must maintain source documentation for all laboratory values reported          |
| 969 | in the candidate's medical chart.   |
| 970 |   |
| 971 | 10.3.C Lung Clinical Values That Must Be Updated When Performed                                       |
| 972 | Transplant hospitals must report updated values for the following clinical values if they were        |
| 973 | updated within any six month period following registration for each candidate at an active or         |
| 974 | inactive status.  |
| 975 | Cardiac index (L/min/m2) at rest, prior to any exercise   |
| 976 | PA mean pressure, if candidate's diagnosis is Sarcoidosis   |
| 977 | <ul> <li>Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise</li> </ul> |
| 978 | The transplant program must maintain source documentation for all laboratory values reported          |
| 979 | in the candidate's medical chart.   |
| 980 |   |
| 001 | 10.4 Eligibility Criteria   |
| 981 | 10.4 Liigibiiity Criteria   |
| 982 |   |
| 983 | 10.4.A Eligibility for Intended Blood Group Incompatible Offers for                                   |
| 984 | Deceased Donor Lungs  |
| 985 | Incompatible blood types are defined in Table 10-2: Incompatible Blood Groups for Deceased            |
| 986 | Donor Lungs.  |
| 987 | Table 10-2: Incompatible Offers Blood Groups for  |
| 988 | Deceased Donor Lungs  |
|     | Deceased Donor's Blood Type Candidate's Blood Type  |
|     | <u> </u>  |
|     | <u>A</u> <u>O and B</u>   |
|     | B O and A   |
|     | AB O, A and B   |
| 989 |   |
| 990 | Candidates with incompatible blood types will be screened from lung match runs unless the             |
| 991 | candidate meets the criteria for eligibility in Table 10-3 below.                                     |
| 992 |   |
| 993 | Table 10-3: Eligibility for Intended Blood Group Incompatible Offers for                              |
| 994 | <u>Deceased Donor Lungs</u>   |
|     | If the candidate is: And meets <i>all</i> of the following:   |
|     | Less than one year old at the 1. Is priority 1  |
|     | time of the match run  2. Has reported isohemagglutinin titer   |
|     | information for A or B blood type antigens  |
|     |   |
|     | to the OPTN within the last 30 days   |



incompatible lung.

| If the candidate is:         | And meets all of the following:                        |
|------------------------------|--|
| At least one year old at the | 1. <u>Is registered prior to turning two years old</u> |
| time of the match run        | 2. <u>Is priority 1</u>                                |
|                              | 3. Has reported to the OPTN                            |
|                              | isohemagglutinin titers less than or equal             |
|                              | to 1:16 for A or B blood type antigens                 |
|                              | from a blood sample collected within the               |
|                              | last 30 days. The candidate must not have              |
|                              | received treatments that may have                      |
|                              | reduced isohemagglutinin titers to 1:16 or             |
|                              | less within 30 days of when this blood                 |
|                              | sample was collected                                   |

# 10.4.B Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood type incompatible lung, according to *Table 10-4* below, at *all* of the following times:

Upon initially reporting that a candidate is willing to accept an intended blood type incompatible lung.
 Every 30 days after initially reporting that a candidate is willing to accept an intended blood type

<u>Table 10-4: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Type</u>
<u>Incompatible Lung</u>

| If the candidate's blood type is: | Then the transplant program must report the following isohemagglutinin titers to the OPTN: |
|-----------------------------------|--|
| <u>A</u>                          | <u>Anti-B</u>  |
| <u>B</u>                          | <u>Anti-A</u>  |
| 0                                 | Anti-A and Anti-B  |

Accurate isohemagglutinin titers must be reported for recipients of an intended blood type incompatible lung, according to *Table 10-5*, as follows:

1. At transplant, from a blood sample taken within 24 hours prior to transplant.

 2. If graft loss occurs within one year after transplant from the most recent sample, if available.

 3. <u>If recipient death occurs within one year after transplant from the most recent blood sample, if</u> available.

#### 1019 <u>Table 10-5: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Type Incompatible Lung</u>

| If the deceased donor's blood type is: | And the recipient's blood type is: | Then the transplant program must report the following isohemagglutinin titers to the OPTN: |
|--|------------------------------------|--|
| <u>A</u>                               | <u>B or O</u>                      | <u>Anti-A</u>  |
| <u>B</u>                               | A or O                             | <u>Anti-B</u>  |
| <u>AB</u>                              | <u>A</u>                           | <u>Anti-B</u>  |
| <u>AB</u>                              | <u>B</u>                           | <u>Anti-A</u>  |
| <u>AB</u>                              | <u>O</u>                           | Anti-A and Anti-B  |

1020

1022

1023

1026

1027

### **Policy 21: Composite Allocation Score Reference**

### **1021 21.1 Formulas**

### 21.1.A Waiting List Survival Formulas

#### 21.1.A.1 Lung Waitlist Area Under the Curve (WLAUC)

The area under the lung waiting list survival probably curve within one year (WLAUC) is calculated using the formula:

 $WL_i = \sum_{k=1}^{365} S_{WL,i}(k-1)$ 

1028 1029

1030

The calculation for  $S_{WL,l}$  is in *Policy 21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year.* 

103110321033

#### 21.1.A.2 Expected Lung Waiting List Survival Probability Within One Year

1034 The formula used to calculate expected lung waiting list survival probability within one year is: 1035

$$S_{\mathsf{WL},i}(\mathsf{t}) = S_{\mathsf{WL},0}(\mathsf{t}) \, e^{\mathbb{E}_1 x_{1i} \mathbb{E}_2 x_{2i} \mathbb{E} \dots \mathbb{E}_p x_{pi}}$$

<u>Table 21-1 lists what each variable in the formula represents.</u>

1040 1041

Table 21-1 Expected Lung Waiting List Survival Probability Within One Year Variables

| The variable                            | <u>Represents</u>  |
|---|--|
| <u>S<sub>WL,i</sub>(t)</u>              | the expected waiting list survival probability at time t for candidate i |
| S <sub>WL,0</sub> (t)                   | the baseline waiting list survival probability at time t                 |
| $\underline{\beta_1, \beta_2, \beta_p}$ | the parameter estimates from the waiting list model (Table 1)            |
| X <sub>ii</sub>                         | the value of characteristic j for candidate i                            |



| The variable | Represents                           |
|--------------|--------------------------------------|
| <u>i</u>     | 1, 2,, N is the candidate identifier |

21.1.A.3 Converting Lung WLAUC to Lung Waiting List Survival Points

1044 Waiting list Survival Points are equal to

1045 1046

 $((25^{(1-WLAUC/365)} - 1)/24)*25$ 

1047 1048

1049

1050

### **21.1.B Post-Transplant Outcomes Formulas**

### 21.1.B.1 Expected 5 years Post-Transplant Area Under the Curve (PTAUC)

The area under the post-transplant survival probably curve during the first 5 years post-transplant year (PTAUC) is calculated using the formula:

10511052

$$\mathsf{PT}_i = \sum_{k=1}^{1625} S_{TX,i}(k)$$

1053 1855 1056

1057

### 21.1.B.2 Expected Lung Post-Transplant Survival Probability Within One Year

The formula used to calculate expected lung waiting list survival probability within one year is:

$$S_{ZX,l}\left(t\right)=S_{ZX,0}\left(t\right)^{e^{2T_{l}+4c_{T}/c_{L}+4c_{T}/c_{L}}}$$

1058 1059

Table 21-1 details what each variable in the formula represents.

1060 1061 1062

Table 21-2 Expected Lung Waiting List Survival Probability Within One Year Variables

| The variable                               | Represents  |
|--|---|
| $\underline{S}_{TX,i}(t)$                  | expected post-transplant survival probability at time t for candidate i |
| <u>S<sub>TX,0</sub>(t)</u>                 | the baseline post-transplant survival probability at time t             |
| $\underline{\alpha_1, \alpha_2, \alpha_q}$ | the parameter estimates from the post-transplant model (Table 2)        |
| Y <sub>ii</sub>                            | the value of characteristic j for candidate i                           |
| <u>i</u>                                   | 1, 2,, N is the candidate identifier                                    |

1063 1064

### 21.1.B.3 Converting Lung PTAUC to Lung Waiting List Survival Points

1065 <u>Waiting list Survival Points are equal to</u>

1066

(PTAUC/1826)\*25

1067 1068

### **21.1.C Biological Disadvantages Formulas**

**21.1.C.1 Lung CPRA Points** 

1070 The Lung CPRA points are equal to

109



1101

1102 1103 1104

| 1071 | ((100 <sup>CPRA</sup> -1)/99)*5  |
|------|--|
| 1072 |  |
| 1073 | The variable CPRA represents the probability of incompatibility based on the candidate's CPRA.   |
| 1074 | 21.2.C.2 Lung Height Points  |
| 1075 | The Lung Height points are equal to  |
| 1076 | $((100^{HTIN}-1)/99)*5$  |
| 1077 |  |
| 1078 | The variable HTIN represents the probability of incompatibility based on the candidate's height  |
| 1079 | found in Policy 21.2.C.1: Probability of Incompatible Lung Donors Based on Height.   |
| 1080 |  |
| 1081 | 21.1.D Efficient Management Formulas   |
| 1082 | 21.1.D.1 Lung Travel Efficiency Points   |
| 1083 | The Lung travel efficiency points are equal to   |
| 1084 | $(I\{NM \le 45\} + I\{NM \in (45,90)\}*(1 - 0.15 / 45 * (NM - 45)) + I\{NM \ge 90\}*0.875 / [1 + exp(0.0025 * 1.05 + 1$ |
| 1085 | (NM – 1500))])*5   |
| 1086 |  |
| 1087 | The variable NM represents straight-line distance between donor hospital and candidate hospital in   |
| 1088 | nautical miles, rounded down to the nearest integer.   |
| 1089 |  |
| 1090 | 21.1.D.2 Lung Proximity Efficiency Points  |
| 1091 | The lung proximity efficiency points are equal to  |
| 1092 |  |
| 1093 | $(1 - [6.3*NM + 247.63*(NM - 43.44)*I{NM > 43.44} - 104.44*(NM - 67.17)*I{NM > 67.17} - 104.44*(NM - $             |
| 1094 | 128.34 * (NM – 86.9) * I{NM > 86.9}] / 116989.1)*5   |
| 1095 |  |
| 1096 | The variable NM represents straight-line distance between donor hospital and candidate hospital in   |
| 1097 | nautical miles, rounded down to the nearest integer.   |
| 1098 |  |
| 1099 | 21.2 Reference Values  |

## 21.2.A Values Used in the Calculation of Lung Waiting List Survival

<u>Table 21-3</u> provides the covariates and their coefficients for the waiting list mortality calculation. See <u>Policy 10.1.F.i: Lung Disease Diagnosis Groups</u> for specific information on each diagnosis group.

<u>Table 21-3: Waiting List Survival Calculation: Covariates and their Coefficients</u>

| For this covariate:                                     | When           | The following coefficient is used in the lung waiting list survival calculation: |
|---|----------------|--|
| Age at the time of the match (fractional calendar year) | all candidates | <u>0.0281444188123287*age</u>  |



| For this covariate:   | When  | The following coefficient is used in the lung waiting list survival calculation: |
|---|---|--|
| Bilirubin (mg/dL) value<br>with the most recent<br>test date and time | bilirubin is more than 1.0 mg/dL                                      | 0.15572123729572*(bilirubin<br>-1)   |
|   | 1.0 mg/dL or less   | <u>0</u>   |
| Body mass index (BMI) (kg/m²)   | BMI less than 20 kg/m <sup>2</sup>                                    | <u>0.10744133677215*(20 – BMI)</u>   |
|   | BMI is at least 20 kg/m <sup>2</sup>                                  | <u>0</u>   |
| <u>Assisted ventilation</u>   | ECMO or continuous mechanical-hospitalized                            | <u>1.57618530736936</u>  |
|   | not ECMO or continuous<br>mechanical-hospitalized                     | 0  |
| Creatinine (serum) (mg/dL) with the most                              | candidate is at least 18 years old                                    | 0.0996197163645* creatinine  |
| recent test date and time   | candidate is less than 18 years old                                   | 0  |
| Diagnosis Group   | <u>A</u>  | <u>0</u>   |
| Diagnosis Group   | <u>B</u>  | <u>1.26319338239175</u>  |
| Diagnosis Group   | <u>C</u>  | 1.78024171092307   |
| Diagnosis Group   | <u>D</u>  | 1.51440083414275   |
| Detailed diagnosis  | Bronchiectasis  | 0.40107198445555   |
| within group A  | Sarcoidosis with PA mean pressure of 30 mm Hg or less                 | 1.39885489102977   |
| Detailed Diagnosis within group D                                     | Pulmonary fibrosis, other specify cause                               | 0.2088684500011  |
|   | Sarcoidosis with PA mean pressure greater than 30 mm                  | -0.64590852776042  |
| <u>Functional Status</u>  | no assistance needed with activities of daily living                  | -0.59790409246653  |
|   | some or total assistance<br>needed with activities of daily<br>living | <u>0</u>   |
| Oxygen needed to  | Diagnosis Group B   | 0.0340531822566417*O <sub>2</sub>  |
| maintain adequate oxygen saturation (88% or greater) at rest (L/min)  | Diagnosis Groups A, C, and D  | 0.08232292818591*O <sub>2</sub>  |
| PCO <sub>2</sub> (mm Hg): current                                     | PCO <sub>2</sub> is at least 40 mm Hg                                 | 0.12639905519026*PCO <sub>2</sub> /10  |
|   | PCO <sub>2</sub> increase is at least 15%                             | 0.15556911866376   |

| For this covariate:   | <u>When</u>  | The following coefficient is used in the lung waiting list survival calculation: |
|---|--|--|
| PCO <sub>2</sub> threshold change   | PCO <sub>2</sub> increase is less than 15%   | <u>0</u>   |
| Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise | Diagnosis Group A and the PA systolic pressure is greater than 40 mm Hg Diagnosis Group A and the PA systolic pressure is 40 mm Hg | 0.55767046368853*(PA<br>systolic – 40)/10<br>0                                   |
|   | or less  Diagnosis Groups B, C, and D  | 0.1230478043299*PA<br>systolic/10  |
| Six-minute-walk distance (feet)   | Obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. | -0.09937981549564*Six-<br>minute-walk distance/100                               |

 If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-4*, then the composite allocation score calculation will substitute normal or least beneficial values to calculate the candidate's waiting list survival score. *Table 21-4* lists the normal and least beneficial values that will be substituted.

Table 21-4: Values Substituted for Missing or Expired Actual Values in Calculating Waiting List Survival Score

| If this covariate's value:              | <u>ls:</u>                               | Then the waiting list survival calculation will use this substituted value: |
|---|--|---|
| Bilirubin                               | Missing, expired, or less than 0.7 mg/dL | <u>0.7 mg/dL</u>  |
| Body mass index (BMI)                   | Missing or expired                       | 100 kg/m <sup>2</sup>   |
| Cardiac index                           | Missing                                  | 3.0 L/min/m <sup>2</sup>  |
| Assisted ventilation                    | Missing or expired                       | No mechanical ventilation   |
| Creatinine: serum                       | Missing or expired                       | 0.1 mg/dL   |
| Functional status                       | Missing or expired                       | No assistance needed in the waiting list model                              |
| Oxygen needed at rest                   | Missing or expired                       | No supplemental oxygen needed   |
| PCO <sub>2</sub>                        | Missing, expired, or less than 40 mm Hg  | 40 mm Hg  |
| Pulmonary artery (PA) systolic pressure | Missing or less than 20 mm Hg            | 20 mm Hg  |



| If this covariate's value: | <u>ls:</u>         | Then the waiting list survival calculation will use this substituted value: |
|----------------------------|--------------------|---|
| Six-minute-walk distance   | Missing or expired | <u>4,000 feet</u>   |

### 21.2.A.1 PCO2 Threshold Change in the Waiting List Survival Calculation

### 

 $\underline{ \mbox{The equation for the PCO}_2 \mbox{ threshold change calculation is:} }$ 

Highest PCO<sub>2</sub> – Lowest PCO<sub>2</sub>
Lowest PCO<sub>2</sub>

<u>Test dates of these highest and lowest values cannot be more than six months apart. The PCO<sub>2</sub> threshold change calculation can use an expired lowest value, but cannot use an expired highest value.</u>

# 21.2.B.2 Probabilities Used in Calculating Lung Waiting List Survival

Table 21-5: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

| <u>T</u>  | <u>S<sub>TX</sub>(t)</u> |
|-----------|--------------------------|
| <u>0</u>  | <u>1</u>                 |
| <u>1</u>  | 0.9999975489             |
| <u>2</u>  | 0.9999827070             |
| <u>3</u>  | 0.9999561442             |
| <u>4</u>  | 0.9999275553             |
| <u>5</u>  | <u>0.9999018223</u>      |
| <u>6</u>  | <u>0.9998777824</u>      |
| <u>7</u>  | <u>0.9998561463</u>      |
| <u>8</u>  | <u>0.9998143795</u>      |
| <u>9</u>  | 0.9997863737             |
| <u>10</u> | 0.9997696882             |
| <u>11</u> | 0.9997397377             |
| <u>12</u> | 0.9997045384             |
| <u>13</u> | 0.9996823002             |
| <u>14</u> | <u>0.9996498264</u>      |
| <u>15</u> | 0.9996353431             |
| <u>16</u> | 0.9996288212             |
| <u>17</u> | <u>0.9996154867</u>      |
| <u>18</u> | <u>0.9995970948</u>      |
| <u>19</u> | 0.9995652300             |
| <u>20</u> | <u>0.9995271489</u>      |
| <u>21</u> | 0.9995080982             |
| <u>22</u> | 0.9994934457             |
| <u>23</u> | 0.9994602264             |
| <u>24</u> | 0.9994302540             |

| <u>T</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>25</u>  | 0.9994060375             |
| <u> 26</u> | 0.9993816059             |
| <u>27</u>  | 0.9993613122             |
| 28         | 0.9993350553             |
| <u>29</u>  | 0.9993022038             |
| 30         | 0.9992938892             |
| <u>31</u>  | 0.9992721423             |
| <u>32</u>  | 0.9992622566             |
| <u>33</u>  | 0.9992427448             |
| <u>34</u>  | 0.9992005080             |
| <u>35</u>  | 0.9991776739             |
| <u>36</u>  | 0.9991551715             |
| <u>37</u>  | 0.9991302006             |
| <u>38</u>  | 0.9991278479             |
| <u>39</u>  | 0.9991028378             |
| <u>40</u>  | 0.9990801777             |
| <u>41</u>  | 0.9990600363             |
| <u>42</u>  | 0.9990482109             |
| <u>43</u>  | 0.9990482109             |
| 44         | 0.9990358743             |
| <u>45</u>  | 0.9990358743             |
| <u>46</u>  | 0.9990016655             |
| <u>47</u>  | 0.9989778087             |
| <u>48</u>  | 0.9989665684             |
| <u>49</u>  | 0.9989492645             |

|           | <u> 3τχ(ι)</u> |
|-----------|----------------|
| <u>50</u> | 0.9989218966   |
| <u>51</u> | 0.9988856853   |
| <u>52</u> | 0.9988518113   |
| <u>53</u> | 0.9988426443   |
| <u>54</u> | 0.9988426443   |
| <u>55</u> | 0.9988209613   |
| <u>56</u> | 0.9988149888   |
| 57        | 0.9987715012   |
| <u>58</u> | 0.9987338578   |
| <u>59</u> | 0.9987247079   |
| <u>60</u> | 0.9987034482   |
| <u>61</u> | 0.9987034482   |
| <u>62</u> | 0.9986649209   |
| <u>63</u> | 0.9986649209   |
| <u>64</u> | 0.9986596474   |
| <u>65</u> | 0.9986301115   |
| <u>66</u> | 0.9986166941   |
| <u>67</u> | 0.9985746371   |
| <u>68</u> | 0.9985695968   |
| <u>69</u> | 0.9985667636   |
| <u>70</u> | 0.9985563118   |
| <u>71</u> | 0.9985101367   |
| <u>72</u> | 0.9984938912   |
| <u>73</u> | 0.9984903590   |
| <u>74</u> | 0.9984305838   |
|           |                |

| Ī         | <u>S<sub>TX</sub>(t)</u> |
|-----------|--------------------------|
| <u>75</u> | 0.9984129085             |
| <u>76</u> | 0.9984027696             |
| <u>77</u> | 0.9983908074             |
| <u>78</u> | 0.9983908074             |
| <u>79</u> | 0.9983787271             |
| <u>80</u> | <u>0.9983696472</u>      |
| <u>81</u> | 0.9983630336             |
| <u>82</u> | <u>0.9983467929</u>      |
| <u>83</u> | 0.9983136954             |
| <u>84</u> | <u>0.9983064970</u>      |
| <u>85</u> | 0.9982951177             |
| <u>86</u> | 0.9982565537             |
| <u>87</u> | 0.9982441865             |
| <u>88</u> | <u>0.9982441865</u>      |
| <u>89</u> | 0.9982441865             |
| <u>90</u> | 0.9982257230             |
| <u>91</u> | 0.9981791418             |
| <u>92</u> | 0.9981791418             |
| <u>93</u> | <u>0.9981714154</u>      |
| <u>94</u> | 0.9981444359             |
| <u>95</u> | 0.9981313503             |
| <u>96</u> | <u>0.9981154417</u>      |
| <u>97</u> | 0.9981154417             |
| <u>98</u> | 0.9980759414             |
| <u>99</u> | 0.9980462038             |

| Ī          | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| 100        | 0.9980462038             |
| 101        | 0.9980357746             |
| 102        | 0.9980357746             |
| 103        | 0.9980261747             |
| <u>104</u> | 0.9979909233             |
| <u>105</u> | 0.9979796304             |
| <u>106</u> | 0.9979796304             |
| <u>107</u> | <u>0.9979760272</u>      |
| <u>108</u> | <u>0.9979646981</u>      |
| <u>109</u> | <u>0.9979440109</u>      |
| <u>110</u> | <u>0.9978768653</u>      |
| <u>111</u> | 0.9978718005             |
| <u>112</u> | 0.9978279771             |
| <u>113</u> | <u>0.9978239640</u>      |
| <u>114</u> | <u>0.9978239640</u>      |
| <u>115</u> | 0.9978239640             |
| <u>116</u> | 0.9978239640             |
| <u>117</u> | <u>0.9978239640</u>      |
| <u>118</u> | <u>0.9978239640</u>      |
| <u>119</u> | 0.9977825323             |
| <u>120</u> | <u>0.9977771080</u>      |
| <u>121</u> | <u>0.9977674724</u>      |
| <u>122</u> | <u>0.9977606316</u>      |
| <u>123</u> | <u>0.9977340449</u>      |
| <u>124</u> | 0.9976558111             |
| <u>125</u> | <u>0.9976558111</u>      |
| <u>126</u> | <u>0.9976504510</u>      |
| <u>127</u> | <u>0.9976370243</u>      |
| <u>128</u> | <u>0.9976101536</u>      |
| <u>129</u> | <u>0.9976101536</u>      |
| <u>130</u> | 0.9976101536             |
| <u>131</u> | 0.9975990034             |
| <u>132</u> | 0.9975835550             |
| <u>133</u> | 0.9975766810             |
| <u>134</u> | 0.9975701094             |
| <u>135</u> | 0.9975701094             |
| <u>136</u> | 0.9975607830             |
| <u>137</u> | 0.9975520103             |
| <u>138</u> | 0.9975404803             |
| <u>139</u> | <u>0.9975404803</u>      |
| <u>140</u> | 0.9975404803             |
| <u>141</u> | 0.9975404803             |
| <u>142</u> | 0.9975404803             |

| Т                 | S <sub>TX</sub> (t)          |
|-------------------|------------------------------|
| 143               | 0.9975344179                 |
| 144               | 0.9975344179                 |
| 145               | 0.9975344179                 |
| 146               | 0.9975298313                 |
| 147               | 0.9975146609                 |
| 148               | 0.9975044749                 |
| 149               | 0.9974993058                 |
| 150               | 0.9974923101                 |
| <u>151</u>        | 0.9974768114                 |
| 152               | 0.9974768114                 |
| <u>153</u>        | 0.9974554527                 |
| <u>154</u>        | <u>0.9974097005</u>          |
| <u>155</u>        | <u>0.9973345023</u>          |
| <u>156</u>        | 0.9973345023                 |
| <u>157</u>        | 0.9973270637                 |
| <u>158</u>        | 0.9973208018                 |
| <u>159</u>        | <u>0.9973148013</u>          |
| <u>160</u>        | 0.9972940898                 |
| <u>161</u>        | 0.9972940898                 |
| <u>162</u>        | <u>0.9972940898</u>          |
| <u>163</u>        | <u>0.9972727684</u>          |
| <u>164</u>        | <u>0.9972727684</u>          |
| <u>165</u>        | <u>0.9972727684</u>          |
| <u>166</u>        | 0.9972688422                 |
| <u>167</u>        | 0.9972234233                 |
| <u>168</u>        | 0.9972234233                 |
| <u>169</u>        | 0.9972179105                 |
| <u>170</u>        | 0.9972086398                 |
| <u>171</u>        | 0.9972086398                 |
| <u>172</u>        | 0.9972086398                 |
| <u>173</u>        | 0.9972086398                 |
| <u>174</u>        | 0.9972086398                 |
| <u>175</u>        | 0.9971827158                 |
| <u>176</u><br>177 | 0.9971692174                 |
|                   | 0.9971692174<br>0.9971692174 |
| 178<br>179        |                              |
| 180               | 0.9971692174<br>0.9971603270 |
| 181               | 0.9971603270                 |
| 182               | 0.9971320838                 |
| 183               | 0.9971131145                 |
| 184               | <u>0.9971131145</u>          |
| 185               | 0.9971091508                 |
| <u> 100</u>       | 0.557 1051500                |

| <u>T</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>186</u> | <u>0.9970985061</u>      |
| <u>187</u> | <u>0.9970985061</u>      |
| <u>188</u> | <u>0.9970985061</u>      |
| <u>189</u> | 0.9970985061             |
| <u>190</u> | 0.9970985061             |
| <u>191</u> | 0.9970985061             |
| <u>192</u> | <u>0.9970985061</u>      |
| <u>193</u> | <u>0.9970985061</u>      |
| <u>194</u> | <u>0.9970911735</u>      |
| <u>195</u> | <u>0.9970671621</u>      |
| <u>196</u> | 0.9969683767             |
| <u>197</u> | 0.9969683767             |
| <u>198</u> | 0.9969683767             |
| <u>199</u> | 0.9969587577             |
| <u>200</u> | 0.9969587577             |
| <u>201</u> | 0.9969454938             |
| <u>202</u> | <u>0.9968612819</u>      |
| <u>203</u> | <u>0.9968383024</u>      |
| <u>204</u> | 0.9968383024             |
| <u>205</u> | 0.9968247526             |
| <u>206</u> | <u>0.9968185781</u>      |
| <u>207</u> | 0.9968185781             |
| <u>208</u> | 0.9968185781             |
| <u>209</u> | 0.9968185781             |
| <u>210</u> | 0.9968097445             |
| <u>211</u> | 0.9967964069             |
| <u>212</u> | 0.9967166260             |
| <u>213</u> | <u>0.9966358744</u>      |
| <u>214</u> | 0.9966212192             |
| <u>215</u> | 0.9966212192             |
| <u>216</u> | 0.9966144147             |
| <u>217</u> | <u>0.9966016656</u>      |
| <u>218</u> | <u>0.9965791846</u>      |
| <u>219</u> | <u>0.9965791846</u>      |
| <u>220</u> | <u>0.9965744007</u>      |
| <u>221</u> | 0.9965236975             |
| <u>222</u> | 0.9965110962             |
| <u>223</u> | 0.9964387358             |
| <u>224</u> | 0.9964387358             |
| <u>225</u> | 0.9964227617             |
| <u>226</u> | 0.9964227617             |
| <u>227</u> | 0.9964120372             |
| <u>228</u> | 0.9963875823             |
|            |                          |

| Ţ          | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| 229        | 0.9963875823             |
| 230        | 0.9963684607             |
| <u>231</u> | 0.9963684607             |
| 232        | 0.9963684607             |
| <u>233</u> | 0.9963684607             |
| 234        | 0.9963684607             |
| <u>235</u> | 0.9963684607             |
| <u>236</u> | <u>0.9963684607</u>      |
| <u>237</u> | 0.9963684607             |
| <u>238</u> | 0.9963684607             |
| <u>239</u> | 0.9963684607             |
| <u>240</u> | <u>0.9963684607</u>      |
| <u>241</u> | 0.9962582929             |
| <u>242</u> | 0.9962582929             |
| <u>243</u> | <u>0.9961947546</u>      |
| <u>244</u> | 0.9961947546             |
| <u>245</u> | <u>0.9961947546</u>      |
| <u>246</u> | <u>0.9960956354</u>      |
| <u>247</u> | <u>0.9960437794</u>      |
| <u>248</u> | <u>0.9960247257</u>      |
| <u>249</u> | <u>0.9959880763</u>      |
| <u>250</u> | <u>0.9959742895</u>      |
| <u>251</u> | <u>0.9959742895</u>      |
| <u>252</u> | <u>0.9959552359</u>      |
| <u>253</u> | <u>0.9959552359</u>      |
| <u>254</u> | <u>0.9959380587</u>      |
| <u>255</u> | <u>0.9959380587</u>      |
| <u>256</u> | <u>0.9959380587</u>      |
| <u>257</u> | <u>0.9959380587</u>      |
| <u>258</u> | <u>0.9959272229</u>      |
| <u>259</u> | <u>0.9959272229</u>      |
| <u>260</u> | 0.9959225083             |
| <u>261</u> | 0.9959225083             |
| <u>262</u> | 0.9959225083             |
| <u>263</u> | 0.9959225083             |
| <u>264</u> | 0.9959225083             |
| <u>265</u> | 0.9959225083             |
| <u>266</u> | 0.9958954164             |
| <u>267</u> | 0.9957938685             |
| <u>268</u> | 0.9957938685             |
| <u>269</u> | 0.9957784566             |
| <u>270</u> | <u>0.9957784566</u>      |
| <u>271</u> | <u>0.9957784566</u>      |

| <u>T</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>272</u> | 0.9957784566             |
| <u>273</u> | 0.9957784566             |
| <u>274</u> | 0.9957702527             |
| 275        | 0.9957639142             |
| <u>276</u> | 0.9957410244             |
| 277        | 0.9957255372             |
| <u>278</u> | 0.9957255372             |
| <u>279</u> | 0.9957255372             |
| <u>280</u> | 0.9957255372             |
| <u>281</u> | 0.9956914479             |
| <u>282</u> | 0.9956914479             |
| <u>283</u> | 0.9956914479             |
| <u>284</u> | 0.9956914479             |
| <u>285</u> | 0.9956797646             |
| <u>286</u> | 0.9956797646             |
| <u>287</u> | 0.9956797646             |
| <u>288</u> | 0.9956605860             |
| <u>289</u> | 0.9956605860             |
| <u>290</u> | 0.9956391439             |
| <u>291</u> | 0.9956391439             |
| <u>292</u> | 0.9955475237             |
| <u>293</u> | 0.9955475237             |
| <u>294</u> | 0.9955054645             |
| <u>295</u> | 0.9954978576             |

| <u>T</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>296</u> | 0.9954793243             |
| <u>297</u> | 0.9954639104             |
| <u>298</u> | 0.9954392804             |
| 299        | 0.9954392804             |
| 300        | 0.9954137179             |
| 301        | 0.9954137179             |
| 302        | 0.9953849510             |
| 303        | 0.9953581531             |
| 304        | 0.9953445180             |
| 305        | 0.9953445180             |
| 306        | 0.9953445180             |
| 307        | 0.9953093054             |
| 308        | 0.9952957037             |
| 309        | 0.9952957037             |
| 310        | 0.9952741113             |
| 311        | 0.9952741113             |
| 312        | 0.9952514686             |
| <u>313</u> | 0.9952514686             |
| 314        | 0.9952514686             |
| <u>315</u> | 0.9952281619             |
| <u>316</u> | 0.9952281619             |
| <u>317</u> | 0.9952281619             |
| 318        | 0.9951666810             |
| 319        | 0.9951314001             |
|            |                          |

| Ţ          | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>320</u> | 0.9951314001             |
| <u>321</u> | 0.9951314001             |
| <u>322</u> | 0.9951314001             |
| <u>323</u> | 0.9951314001             |
| <u>324</u> | 0.9950798577             |
| <u>325</u> | 0.9950798577             |
| <u>326</u> | 0.9950798577             |
| <u>327</u> | 0.9950798577             |
| <u>328</u> | 0.9950798577             |
| <u>329</u> | 0.9950798577             |
| <u>330</u> | 0.9950798577             |
| <u>331</u> | 0.9950798577             |
| <u>332</u> | 0.9950670017             |
| <u>333</u> | 0.9949858453             |
| <u>334</u> | 0.9949512121             |
| <u>335</u> | 0.9949512121             |
| <u>336</u> | 0.9949512121             |
| <u>337</u> | 0.9949369873             |
| <u>338</u> | 0.9949369873             |
| <u>339</u> | 0.9949369873             |
| <u>340</u> | 0.9949369873             |
| <u>341</u> | 0.99493698171325         |
| <u>342</u> | 0.9949369873             |
| <u>343</u> | 0.9949369873             |
|            |                          |

| Ţ          | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|
| <u>344</u> | 0.9948416999             |
| <u>345</u> | 0.9948416999             |
| <u>346</u> | 0.9948416999             |
| <u>347</u> | 0.9947378061             |
| <u>348</u> | 0.9946948263             |
| <u>349</u> | 0.9946845005             |
| <u>350</u> | 0.9946845005             |
| <u>351</u> | 0.9946845005             |
| <u>352</u> | 0.9946845005             |
| <u>353</u> | 0.9946845005             |
| <u>354</u> | 0.9945854823             |
| <u>355</u> | 0.9945854823             |
| <u>356</u> | 0.9945720480             |
| <u>357</u> | 0.9945265776             |
| <u>358</u> | 0.9945265776             |
| <u>359</u> | 0.9945265776             |
| <u>360</u> | 0.9944766010             |
| <u>361</u> | 0.9944766010             |
| <u>362</u> | 0.9944766010             |
| <u>363</u> | 0.9944766010             |
| <u>364</u> | 0.9943896539             |

11261127

1128

1129

1130

### 21.2.B Values Used in the Calculation of Post-Transplant Outcomes

### 21.2.B.1 Coefficients Used in Calculating Lung Post-Transplant Outcomes

<u>Table 21-6 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See Policy 10.1.F.i: Lung Disease Diagnosis Groups for specific information on each diagnosis group.</u>

1131 1132 1133

Table 21-6: Post-Transplant Outcomes Calculation: Covariates and Their Coefficients

| For this covariate                                      | When                                   | The following is used in the lung post-transplant outcomes score calculation |
|---|--|--|
|   | age is less than 20                    | 0.06763086 x (20 - age) +<br>0.78241832                                      |
| Age at the time of the match (fractional calendar year) | age is at least 20 and less than 30,   | -0.07824183 x (age - 20) +<br>0.78241832                                     |
|   | age is at least 30 and less<br>than 40 | <u>0</u>   |



| For this covariate                                      | <u>When</u>  | The following is used in the lung post-transplant outcomes score calculation      |
|---|--|---|
|   | age is at least 40 and less<br>than 50   | 0.00259081 x (age - 40)   |
|   | age is at least 50 and less<br>than 60   | 0.01674634 x (age - 50) +<br>0.02590812   |
|   | age is at least 60 and less<br>than 70   | 0.02271446 x (age - 60) +<br>0.19337148   |
|   | age is greater than 70   | 0.06122886 x (age - 70) +<br>0.42051611   |
|   | creatinine is less than 0.4  | -7.40167261 x (0.4 -<br>creatinine) + 0.41872820                                  |
| Creatinine (serum) (mg/dL)                              | creatinine is at least 0.4 and less than 0.6                                     | -1.25841033 x (creatinine -<br>0.4) + 0.41872820                                  |
| with the most recent data<br>and time                   | creatinine is at least 0.6 and less than 0.8                                     | 0.37123489 x (creatinine -<br>0.6) + 0.16704614                                   |
|   | creatinine is at least 0.8 and less than 1.4                                     | 0.68443018 x (creatinine -<br>0.8) + 0.24129311                                   |
|   | creatinine is at least 1.4   | 0.68818942 x (creatinine -<br>1.4) + 0.65195122                                   |
|   | Less than 2 L/min/m <sup>2</sup>   | -0.48374911 x (2 – cardiac<br>index) + 0.04030226                                 |
|   | At least 2 and less than 2.5 L/min/m <sup>2</sup>                                | -0.08060453 x (cardiac<br>index - 2) + 0.04030226                                 |
| Cardiac index (L/min/m²) at rest, prior to any exercise | At least 2.5 and less than 3.5 L/min/m <sup>2</sup>                              | 0.01361694 x (cardiac index<br>-2.5)  |
|   | At least 3.5 and less than 4.5 L/min/m <sup>2</sup> At least 4.5 and less than 5 | 0.08084326 x (cardiac index<br>- 3.5) + 0.01361694<br>0.06969388 x (cardiac index |
|   | L/min/m <sup>2</sup> ECMO or continuous  | -4.5) + 0.09446020<br>0.267537018672253   |
| Assisted ventilation                                    | mechanical-hospitalized not ECMO or continuous                                   | <u>0.207337018072233</u><br><u>0</u>  |
|   | mechanical-hospitalized  Performs activities of daily                            | -0.00530412   |
|   | living with no assistance  Performs activities of daily                          | <u> </u>  |
| <u>Functional status</u>                                | living with some assistance Performs activities of daily                         | <u>0.07437840</u>   |
|   | living with total assistance  A  | <u>-0.0989</u>  |
| <u>Diagnosis Group</u>                                  | <u>B</u> <u>C</u>  | <u>0</u><br>-0.16713  |
|   | <u>D</u>   | 0   |

| For this covariate   | <u>When</u>   | The following is used in the lung post-transplant outcomes score calculation |
|--|---|--|
|  | <u>Diagnosis is Bronchiectasis</u>  | <u>-0.02670666</u>   |
| Detailed diagnosis within<br>Group A   | <u>Diagnosis is Sarcoidosis</u><br>with PA mean pressure of<br>30 mm Hg or less                 | 0.501743373724746  |
|  | <u>Diagnosis is</u><br><u>lymphangioleiomyomatosis</u>  | <u>-0.271420386</u>  |
|  | <u>Diagnosis is Obliterative</u><br><u>bronchiolitis (not-</u><br><u>retransplant)</u>          | -0.13263   |
| Detailed diagnosis within Group D  | <u>Diagnosis is Sarcoidosis</u><br><u>with PA mean pressure</u><br><u>greater than 30 mm Hg</u> | 0.0561853179859775   |
|  | Diagnosis is pulmonary fibrosis, not idiopathic   | 0.046504644  |
| Six-minute-walk distance   | six-minute-walk distance is<br>less than 200 feet   | -0.00025351 x (200 - Six-<br>minute-walk distance) +<br>0.11168755           |
| (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test. | six-minute-walk distance is<br>at least 200 feet and less<br>than 600 feet                      | <u>-0.00028418 x (Six-minute-walk distance - 200) + 0.11168755</u>           |
|  | six-minute-walk distance is<br>at least 600 feet and less<br>than 800 feet                      | -0.00000496 x (Six-minute-<br>walk distance - 600) -<br>0.00198468           |
|  | six-minute-walk distance is<br>at least 800 feet and less<br>than 1,200 feet                    | <u>-0.00019505 x (Six-minute-walk distance - 800) - 0.00297703</u>           |
|  | six-minute-walk distance is<br>at least 1,200 feet  | -0.00074286 x (Six-minute-<br>walk distance - 1200) -<br>0.08099560          |

1135 1136 1137

1138

1139

If values for certain covariates are missing, expired, or below the threshold as defined by Table 10-4, then the composite allocation score calculation will substitute normal or least beneficial values to calculate the candidate's post-transplant outcomes score. Table 21-7 lists the normal and least beneficial values that will be substituted.

### 1140 <u>Table 21-7: Values Substituted for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes Score</u>

| If this covariate's value:              | <u>ls:</u>  | Then the post-transplant outcomes score calculation will use this substituted value: |
|---|---|--|
| <u>Cardiac index</u>                    | Missing, or greater than 5                                    | 5.0 L/min/m <sup>2</sup>   |
| Continuous mechanical ventilation       | Missing or expired  | Continuous mechanical ventilation while hospitalized                                 |
| Creatinine: serum                       | Missing, expired or greater than 1.6                          | 1.6 mg/dL  |
| <u>Functional status</u>                | Missing or expired  | Total assistance needed  |
| Pulmonary artery (PA) systolic pressure | Missing or less than 20 mm Hg and the candidate is in Group A | 20 mm Hg   |
|   | Missing or expired and the candidate is in Group D            | 40 mm Hg   |
| Civ minute well distance                | Missing or expired  | <u>200 feet</u>  |
| Six-minute-walk distance                | Greater than 1,600  | <u>1,600 feet</u>  |

11411142

### 21.2.B.2 Probabilities Used in Calculating Lung Post-Transplant Survival

1143

### $\underline{\textbf{Table 21-8: Baseline Post-Transplant Survival (S_{TX}(\underline{\textbf{t}})) \ Probability \ Where \ \textbf{t=Time in Days}}$

1144

| <u>t</u>  | <u>S<sub>TX</sub>(t)</u> |
|-----------|--------------------------|
| <u>1</u>  | 0.999154                 |
| <u>2</u>  | 0.998058                 |
| <u>3</u>  | <u>0.997111</u>          |
| <u>4</u>  | <u>0.996312</u>          |
| <u>5</u>  | <u>0.995562</u>          |
| <u>6</u>  | <u>0.995162</u>          |
| <u>7</u>  | <u>0.994562</u>          |
| <u>8</u>  | <u>0.994011</u>          |
| <u>9</u>  | 0.99336                  |
| <u>10</u> | <u>0.992859</u>          |
| <u>11</u> | <u>0.992107</u>          |
| <u>12</u> | <u>0.991806</u>          |
| <u>13</u> | <u>0.991154</u>          |
| <u>14</u> | 0.990802                 |
| <u>15</u> | <u>0.99025</u>           |
| <u>16</u> | 0.989747                 |
| <u>17</u> | 0.989294                 |
| <u>18</u> | 0.988942                 |
| <u>19</u> | <u>0.98864</u>           |

| <u>t</u>  | <u>S<sub>TX</sub>(t)</u> |
|-----------|--------------------------|
| <u>20</u> | 0.988287                 |
| <u>21</u> | <u>0.988086</u>          |
| <u>22</u> | <u>0.987633</u>          |
| <u>23</u> | <u>0.98738</u>           |
| <u>24</u> | <u>0.986977</u>          |
| <u>25</u> | <u>0.986574</u>          |
| <u>26</u> | <u>0.986473</u>          |
| <u>27</u> | <u>0.986069</u>          |
| <u>28</u> | <u>0.985917</u>          |
| <u>29</u> | <u>0.985463</u>          |
| <u>30</u> | <u>0.984907</u>          |
| <u>31</u> | <u>0.984705</u>          |
| <u>32</u> | <u>0.984048</u>          |
| <u>33</u> | <u>0.983592</u>          |
| <u>34</u> | <u>0.98344</u>           |
| <u>35</u> | 0.983238                 |
| <u>36</u> | <u>0.982731</u>          |
| <u>37</u> | 0.982478                 |
| <u>38</u> | <u>0.982225</u>          |

| <u>39</u> | 0.981616 |
|-----------|----------|
| <u>40</u> | 0.981363 |
| <u>41</u> | 0.981007 |
| <u>42</u> | 0.980957 |
| <u>43</u> | 0.980652 |
| <u>44</u> | 0.980297 |
| <u>45</u> | 0.980144 |
| <u>46</u> | 0.980043 |
| <u>47</u> | 0.97989  |
| <u>48</u> | 0.979687 |
| <u>49</u> | 0.979484 |
| <u>51</u> | 0.979179 |
| <u>52</u> | 0.978772 |
| <u>54</u> | 0.978467 |
| <u>55</u> | 0.978162 |
| <u>56</u> | 0.977857 |
| <u>57</u> | 0.977653 |
| <u>58</u> | 0.977347 |
| <u>59</u> | 0.977195 |
|           |          |

<u>S<sub>TX</sub>(t)</u>

| <u>T</u>  | <u> S<sub>TX</sub>(τ)</u> |
|-----------|---------------------------|
| <u>60</u> | 0.977042                  |
| <u>61</u> | 0.976634                  |
| <u>62</u> | 0.976431                  |
| <u>63</u> | 0.976125                  |
| <u>64</u> | 0.976074                  |
| <u>65</u> | 0.975921                  |
| <u>66</u> | 0.975717                  |
| <u>67</u> | 0.975666                  |
| <u>68</u> | 0.975513                  |
| <u>69</u> | 0.975411                  |
| <u>70</u> | <u>0.975156</u>           |
| <u>71</u> | 0.974748                  |
| <u>72</u> | 0.974645                  |
| <u>73</u> | 0.974441                  |
| <u>74</u> | 0.974339                  |
| <u>77</u> | 0.974288                  |
| <u>78</u> | <u>0.974186</u>           |
| <u>79</u> | <u>0.974083</u>           |
| 80        | 0.973981                  |

t S=v(t)

| <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | S <sub>TX</sub> (t) | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|------------|---------------------|------------|--------------------------|------------|--------------------------|
| 81         | 0.973879                 | 128        | 0.966903            | <u>173</u> | 0.961017                 | 216        | 0.954156                 |
| 82         | 0.973828                 | 129        | 0.966852            | <u>174</u> | 0.960913                 | 217        | 0.954052                 |
| 83         | 0.973726                 | 130        | 0.966749            | <u>175</u> | 0.960706                 | 218        | 0.954                    |
| 84         | 0.973675                 | 131        | 0.966697            | <u>176</u> | 0.96055                  | 219        | 0.953843                 |
| 85         | 0.973572                 | 132        | 0.966646            | <u>177</u> | 0.960447                 | 220        | 0.953739                 |
| <u>86</u>  | 0.97347                  | 133        | 0.966543            | <u>178</u> | 0.960239                 | <u>221</u> | 0.953634                 |
| <u>87</u>  | 0.973214                 | 135        | 0.96644             | <u>179</u> | 0.960187                 | 222        | 0.953478                 |
| <u>88</u>  | 0.972908                 | 136        | 0.966388            | <u>180</u> | 0.960032                 | 223        | 0.953269                 |
| <u>89</u>  | 0.972703                 | <u>137</u> | 0.966131            | <u>181</u> | 0.959928                 | 224        | 0.95306                  |
| <u>90</u>  | 0.972549                 | <u>138</u> | 0.965925            | <u>182</u> | 0.959876                 | <u>225</u> | 0.952956                 |
| <u>92</u>  | 0.972396                 | <u>140</u> | 0.965615            | <u>183</u> | 0.959565                 | <u>226</u> | 0.952799                 |
| <u>94</u>  | 0.972242                 | <u>141</u> | 0.965461            | <u>184</u> | 0.959513                 | <u>227</u> | 0.952642                 |
| <u>95</u>  | 0.971884                 | <u>142</u> | <u>0.965358</u>     | <u>185</u> | <u>0.959358</u>          | <u>228</u> | 0.952329                 |
| <u>97</u>  | 0.971782                 | <u>143</u> | <u>0.965254</u>     | <u>186</u> | 0.95915                  | <u>229</u> | 0.952277                 |
| <u>98</u>  | 0.971474                 | <u>144</u> | <u>0.965151</u>     | <u>187</u> | 0.958994                 | <u>230</u> | 0.952016                 |
| <u>99</u>  | 0.971423                 | <u>145</u> | 0.964842            | <u>188</u> | 0.958943                 | <u>231</u> | 0.951963                 |
| <u>100</u> | 0.971064                 | <u>146</u> | 0.96479             | <u>189</u> | 0.958839                 | <u>232</u> | 0.951702                 |
| <u>101</u> | 0.970808                 | <u>147</u> | <u>0.964481</u>     | <u>190</u> | 0.958579                 | <u>233</u> | 0.95165                  |
| <u>102</u> | 0.970757                 | <u>148</u> | <u>0.964377</u>     | <u>191</u> | <u>0.958475</u>          | <u>234</u> | <u>0.95144</u>           |
| <u>103</u> | 0.970552                 | <u>149</u> | 0.964223            | <u>192</u> | 0.958164                 | <u>235</u> | <u>0.951074</u>          |
| <u>104</u> | 0.970398                 | <u>150</u> | 0.964068            | <u>193</u> | 0.958008                 | <u>236</u> | 0.950813                 |
| <u>106</u> | 0.970346                 | <u>151</u> | 0.963913            | <u>194</u> | <u>0.957852</u>          | <u>237</u> | 0.950603                 |
| <u>107</u> | 0.970193                 | <u>153</u> | 0.963655            | <u>195</u> | <u>0.9578</u>            | <u>238</u> | 0.950446                 |
| <u>108</u> | 0.969987                 | <u>154</u> | 0.963345            | <u>197</u> | <u>0.957644</u>          | <u>239</u> | 0.950342                 |
| <u>109</u> | 0.969885                 | <u>155</u> | 0.963241            | <u>198</u> | 0.957384                 | <u>241</u> | 0.950289                 |
| <u>110</u> | 0.969731                 | <u>156</u> | 0.963138            | <u>199</u> | 0.957176                 | <u>242</u> | 0.950185                 |
| <u>111</u> | 0.969474                 | <u>157</u> | 0.963035            | <u>200</u> | 0.957072                 | <u>243</u> | 0.950028                 |
| <u>112</u> | 0.969423                 | <u>158</u> | 0.96288             | <u>201</u> | 0.956864                 | <u>244</u> | 0.949923                 |
| <u>113</u> | 0.969269                 | <u>159</u> | 0.962724            | <u>202</u> | 0.956604                 | <u>245</u> | 0.949713                 |
| <u>114</u> | 0.969115                 | <u>160</u> | 0.962621            | <u>203</u> | 0.956396                 | <u>247</u> | 0.949556                 |
| <u>115</u> | 0.968755                 | <u>161</u> | 0.962518            | <u>204</u> | <u>0.95624</u>           | <u>249</u> | 0.949399                 |
| <u>116</u> | 0.968652                 | <u>162</u> | <u>0.962414</u>     | <u>205</u> | 0.955928                 | <u>250</u> | 0.949137                 |
| <u>117</u> | 0.968395                 | <u>163</u> | <u>0.962311</u>     | <u>206</u> | 0.955824                 | <u>251</u> | 0.949085                 |
| <u>118</u> | 0.968292                 | <u>164</u> | 0.962207            | <u>207</u> | 0.955772                 | <u>252</u> | 0.949032                 |
| <u>119</u> | 0.967984                 | <u>165</u> | 0.962052            | <u>208</u> | 0.955511                 | <u>253</u> | <u>0.94898</u>           |
| <u>120</u> | 0.967932                 | <u>166</u> | 0.961845            | <u>209</u> | 0.955303                 | <u>254</u> | <u>0.94877</u>           |
| <u>121</u> | 0.967675                 | <u>167</u> | 0.961741            | <u>210</u> | 0.955147                 | <u>255</u> | 0.948613                 |
| <u>122</u> | 0.967572                 | <u>168</u> | 0.961638            | <u>211</u> | 0.954886                 | <u>256</u> | 0.948193                 |
| <u>123</u> | 0.967469                 | <u>169</u> | <u>0.961586</u>     | <u>212</u> | <u>0.95473</u>           | <u>257</u> | 0.947931                 |
| <u>124</u> | 0.967315                 | <u>170</u> | <u>0.961483</u>     | <u>213</u> | <u>0.954678</u>          | <u>258</u> | <u>0.947826</u>          |
| <u>125</u> | 0.967161                 | <u>171</u> | <u>0.961275</u>     | <u>214</u> | 0.954469                 | <u>259</u> | <u>0.947774</u>          |
| <u>127</u> | 0.966955                 | <u>172</u> | 0.961224            | <u>215</u> | 0.954313                 | <u>260</u> | <u>0.947616</u>          |

| <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |          | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|----------|-------------|--------------------------|------------|--------------------------|------------|--------------------------|
| <u>261</u> | 0.947459                 | 3        | 307         | 0.941352                 | <u>350</u> | 0.935259                 | 399        | 0.927207                 |
| <u>262</u> | 0.947406                 | 13       | 308         | 0.941193                 | <u>352</u> | 0.935047                 | <u>400</u> | 0.926993                 |
| 263        | 0.947301                 | <u>;</u> | 309         | 0.940982                 | <u>353</u> | 0.934887                 | <u>401</u> | 0.926886                 |
| 264        | 0.947196                 | <u>;</u> | 310         | 0.940876                 | <u>354</u> | 0.934728                 | 402        | 0.926725                 |
| 265        | 0.946986                 |          | 311         | 0.940771                 | <u>356</u> | 0.934675                 | 404        | 0.926618                 |
| <u>266</u> | 0.946881                 | 13       | 312         | 0.940559                 | <u>357</u> | 0.934462                 | <u>405</u> | 0.926457                 |
| <u>267</u> | 0.946724                 | 3        | <u>313</u>  | 0.9404                   | <u>358</u> | 0.934196                 | <u>406</u> | 0.926189                 |
| <u>268</u> | 0.946566                 | 3        | 314         | 0.940295                 | <u>359</u> | 0.934037                 | <u>407</u> | 0.926136                 |
| <u>269</u> | 0.946461                 | 3        | <u>315</u>  | 0.940189                 | <u>360</u> | 0.933877                 | <u>408</u> | 0.925975                 |
| <u>270</u> | 0.946198                 | 3        | 31 <u>6</u> | 0.94003                  | <u>361</u> | 0.933664                 | <u>409</u> | 0.925921                 |
| <u>271</u> | 0.945935                 | 3        | 317         | 0.939925                 | <u>366</u> | 0.933505                 | <u>410</u> | 0.925868                 |
| <u>273</u> | 0.94583                  | 3        | <u>318</u>  | 0.939766                 | <u>367</u> | 0.933239                 | <u>411</u> | 0.925707                 |
| <u>274</u> | 0.945778                 |          | <u>319</u>  | 0.939713                 | <u>368</u> | <u>0.932866</u>          | <u>412</u> | <u>0.925439</u>          |
| <u>275</u> | 0.945567                 |          | <u>320</u>  | 0.93966                  | <u>369</u> | 0.932653                 | <u>414</u> | 0.925332                 |
| <u>276</u> | 0.945462                 |          | <u>321</u>  | 0.939607                 | <u>370</u> | 0.932546                 | <u>416</u> | 0.925117                 |
| <u>277</u> | <u>0.94541</u>           |          | <u> 322</u> | 0.939501                 | <u>371</u> | <u>0.93228</u>           | <u>417</u> | <u>0.925063</u>          |
| <u>278</u> | <u>0.945199</u>          | <u>;</u> | <u>323</u>  | 0.939342                 | <u>372</u> | <u>0.931854</u>          | <u>418</u> | <u>0.924956</u>          |
| <u>279</u> | 0.945147                 |          | <u>325</u>  | 0.939078                 | <u>373</u> | <u>0.931801</u>          | <u>419</u> | 0.924634                 |
| <u>280</u> | <u>0.944989</u>          | 3        | <u> 326</u> | <u>0.938972</u>          | <u>374</u> | <u>0.931747</u>          | <u>421</u> | <u>0.924581</u>          |
| <u>281</u> | <u>0.944936</u>          | <u>;</u> | <u>327</u>  | <u>0.938919</u>          | <u>375</u> | <u>0.931641</u>          | <u>422</u> | <u>0.92442</u>           |
| <u>282</u> | <u>0.944831</u>          | <u>;</u> | <u>328</u>  | <u>0.938707</u>          | <u>376</u> | <u>0.931481</u>          | <u>423</u> | <u>0.924312</u>          |
| <u>283</u> | <u>0.94462</u>           | <u>;</u> | <u>329</u>  | <u>0.938495</u>          | <u>377</u> | <u>0.931374</u>          | <u>424</u> | <u>0.924205</u>          |
| <u>285</u> | <u>0.944515</u>          | <u>;</u> | <u>330</u>  | <u>0.938389</u>          | <u>378</u> | <u>0.931267</u>          | <u>425</u> | <u>0.923829</u>          |
| <u>286</u> | 0.944357                 | <u>:</u> | <u> 331</u> | 0.938177                 | <u>379</u> | 0.930947                 | <u>426</u> | <u>0.92356</u>           |
| <u>287</u> | 0.944094                 | <u>;</u> | <u>332</u>  | 0.938124                 | <u>381</u> | <u>0.930787</u>          | <u>427</u> | <u>0.923507</u>          |
| <u>288</u> | 0.943936                 | <u>;</u> | <u>333</u>  | 0.937913                 | <u>382</u> | <u>0.930627</u>          | <u>428</u> | <u>0.923292</u>          |
| <u>289</u> | 0.943831                 | <u>;</u> | <u>334</u>  | <u>0.937701</u>          | <u>383</u> | 0.930147                 | <u>429</u> | 0.923184                 |
| <u>290</u> | 0.943673                 | <u>;</u> | <u> 335</u> | <u>0.937435</u>          | <u>384</u> | 0.929987                 | <u>431</u> | <u>0.92313</u>           |
| <u>291</u> | <u>0.943356</u>          | <u>:</u> | <u> 336</u> | 0.93717                  | <u>385</u> | <u>0.929666</u>          | <u>432</u> | 0.922969                 |
| <u>292</u> | 0.943198                 | <u>:</u> | <u> 337</u> | <u>0.936905</u>          | <u>386</u> | <u>0.929506</u>          | <u>433</u> | 0.922915                 |
| <u>293</u> | 0.942987                 | <u>:</u> | <u>338</u>  | 0.93664                  | <u>387</u> | 0.929453                 | <u>434</u> | 0.922646                 |
| <u>294</u> | 0.942882                 | <u>:</u> | <u> 339</u> | 0.936534                 | <u>388</u> | 0.929292                 | <u>435</u> | 0.922485                 |
| <u>295</u> | 0.942777                 | <u>:</u> | <u>340</u>  | 0.936428                 | <u>389</u> | 0.929079                 | <u>436</u> | 0.922377                 |
| <u>297</u> | 0.942513                 | <u>:</u> | <u>341</u>  | 0.936162                 | <u>390</u> | <u>0.928865</u>          | <u>437</u> | 0.922108                 |
| <u>298</u> | <u>0.94246</u>           | <u>:</u> | <u>342</u>  | 0.936056                 | <u>391</u> | 0.928811                 | <u>438</u> | <u>0.922001</u>          |
| <u>299</u> | 0.942302                 | <u> </u> | <u>343</u>  | 0.936003                 | <u>392</u> | 0.928704                 | <u>439</u> | 0.921839                 |
| <u>300</u> | 0.942196                 | <u> </u> | <u>344</u>  | <u>0.93595</u>           | <u>393</u> | 0.928277                 | <u>440</u> | <u>0.92157</u>           |
| <u>301</u> | 0.941985                 | <u>:</u> | <u>345</u>  | 0.935897                 | <u>394</u> | <u>0.92817</u>           | <u>441</u> | 0.921409                 |
| <u>303</u> | 0.941827                 | <u>:</u> | <u>346</u>  | 0.935737                 | <u>395</u> | 0.927956                 | <u>442</u> | 0.921355                 |
| <u>304</u> | 0.941774                 | <u> </u> | <u>347</u>  | 0.935631                 | <u>396</u> | 0.927849                 | <u>443</u> | <u>0.921301</u>          |
| <u>305</u> | <u>0.94151</u>           | <u> </u> | <u>348</u>  | 0.935578                 | <u>397</u> | 0.927421                 | <u>444</u> | 0.921247                 |
| <u>306</u> | 0.941405                 | <u> </u> | <u>349</u>  | 0.935472                 | <u>398</u> | <u>0.927368</u>          | <u>445</u> | <u>0.921193</u>          |

| <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |           | <u>t</u> | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|-----------|----------|--------------------------|------------|--------------------------|------------|--------------------------|
| 446        | 0.921139                 | 49        | 4        | 0.914709                 | 539        | 0.908618                 | 585        | 0.90249                  |
| 447        | 0.920816                 | 49        | 5        | 0.914655                 | 541        | 0.908455                 | 586        | 0.902269                 |
| 448        | 0.920708                 | 49        | 6        | 0.914492                 | 542        | 0.908291                 | 587        | 0.902159                 |
| 449        | 0.920493                 | 49        | 7        | 0.914221                 | 543        | 0.908073                 | 588        | 0.902104                 |
| 450        | 0.920277                 | 49        | 8        | 0.914112                 | 544        | 0.908018                 | 589        | 0.902049                 |
| <u>451</u> | 0.920223                 | 49        | 9        | 0.914058                 | <u>545</u> | 0.9078                   | <u>590</u> | 0.901938                 |
| <u>452</u> | 0.920062                 | <u>50</u> | 0        | 0.913949                 | <u>546</u> | 0.907745                 | <u>591</u> | 0.901883                 |
| <u>453</u> | 0.9199                   | <u>50</u> | 1        | 0.913841                 | <u>547</u> | 0.907636                 | <u>592</u> | 0.901773                 |
| <u>454</u> | 0.919846                 | <u>50</u> | 2        | 0.913732                 | <u>548</u> | 0.907527                 | <u>593</u> | 0.901662                 |
| <u>455</u> | 0.919576                 | <u>50</u> | 3        | 0.913461                 | <u>549</u> | 0.907472                 | <u>594</u> | 0.901607                 |
| <u>456</u> | 0.919361                 | <u>50</u> | 4        | 0.913352                 | <u>550</u> | 0.907254                 | <u>595</u> | 0.901551                 |
| <u>457</u> | 0.919199                 | <u>50</u> | 5        | 0.913243                 | <u>551</u> | 0.907144                 | <u>596</u> | 0.901496                 |
| <u>458</u> | 0.919091                 | <u>50</u> | <u>6</u> | <u>0.913026</u>          | <u>552</u> | <u>0.906926</u>          | <u>597</u> | 0.901496                 |
| <u>459</u> | 0.918983                 | <u>50</u> | 7        | 0.912972                 | <u>553</u> | <u>0.906871</u>          | <u>598</u> | 0.90133                  |
| <u>460</u> | 0.918821                 | <u>50</u> | <u>8</u> | <u>0.912809</u>          | <u>554</u> | 0.906817                 | <u>599</u> | 0.90133                  |
| <u>462</u> | <u>0.918659</u>          | <u>50</u> | 9        | 0.912592                 | <u>555</u> | 0.906598                 | <u>600</u> | 0.901274                 |
| <u>463</u> | 0.918389                 | <u>51</u> | 0        | 0.912429                 | <u>556</u> | 0.90627                  | <u>601</u> | 0.901274                 |
| <u>464</u> | 0.918173                 | <u>51</u> | <u>1</u> | 0.912265                 | <u>557</u> | 0.906161                 | <u>602</u> | 0.901051                 |
| <u>465</u> | 0.918119                 | <u>51</u> | 2        | 0.912157                 | <u>559</u> | 0.906051                 | <u>603</u> | 0.900829                 |
| <u>466</u> | 0.917795                 | <u>51</u> | 3        | 0.911939                 | <u>560</u> | 0.905723                 | <u>604</u> | 0.900773                 |
| <u>467</u> | 0.917632                 | <u>51</u> | 4        | 0.911776                 | <u>561</u> | 0.905559                 | <u>605</u> | 0.900662                 |
| <u>468</u> | 0.917416                 | <u>51</u> | <u>5</u> | 0.911613                 | <u>562</u> | 0.90534                  | <u>606</u> | 0.90055                  |
| <u>469</u> | 0.917308                 | <u>51</u> | <u>6</u> | 0.911232                 | <u>563</u> | 0.905231                 | <u>607</u> | 0.900438                 |
| <u>470</u> | 0.917254                 | <u>51</u> | 7        | 0.911069                 | <u>564</u> | 0.905121                 | <u>608</u> | 0.900326                 |
| <u>471</u> | 0.917092                 | <u>51</u> | 8        | 0.910797                 | <u>567</u> | 0.904902                 | <u>609</u> | 0.90027                  |
| <u>472</u> | <u>0.916875</u>          | <u>51</u> | 9        | 0.910688                 | <u>568</u> | 0.904738                 | <u>610</u> | 0.900103                 |
| <u>473</u> | 0.916821                 | <u>52</u> | 0        | 0.910525                 | <u>569</u> | 0.904574                 | <u>611</u> | 0.900103                 |
| <u>474</u> | <u>0.916659</u>          | <u>52</u> | 2        | <u>0.910471</u>          | <u>570</u> | 0.90441                  | <u>612</u> | 0.899934                 |
| <u>475</u> | 0.916442                 | <u>52</u> | <u>3</u> | 0.910362                 | <u>571</u> | 0.904355                 | <u>613</u> | 0.89971                  |
| <u>477</u> | 0.916388                 | <u>52</u> | 4        | 0.910253                 | <u>572</u> | 0.904245                 | <u>614</u> | 0.899654                 |
| <u>478</u> | <u>0.91628</u>           | <u>52</u> | <u>5</u> | 0.910144                 | <u>573</u> | 0.904136                 | <u>615</u> | 0.899485                 |
| <u>479</u> | 0.916172                 | <u>52</u> | <u>6</u> | 0.909926                 | <u>574</u> | 0.903971                 | <u>616</u> | 0.899317                 |
| <u>480</u> | 0.916117                 | <u>52</u> | <u>7</u> | 0.909872                 | <u>575</u> | 0.903862                 | <u>617</u> | 0.899204                 |
| <u>481</u> | 0.916009                 | <u>52</u> | 8        | 0.909817                 | <u>576</u> | 0.903643                 | <u>618</u> | 0.899148                 |
| <u>482</u> | 0.915955                 | <u>53</u> | 0        | 0.909599                 | <u>577</u> | 0.903533                 | <u>619</u> | 0.899035                 |
| <u>483</u> | 0.915793                 | <u>53</u> | <u>1</u> | 0.90949                  | <u>578</u> | 0.903259                 | <u>620</u> | 0.898979                 |
| <u>484</u> | 0.915522                 | <u>53</u> | 2        | 0.909436                 | <u>579</u> | 0.903149                 | <u>621</u> | 0.898866                 |
| <u>485</u> | 0.915413                 | <u>53</u> |          | 0.909381                 | <u>580</u> | 0.903094                 | <u>622</u> | 0.898866                 |
| <u>487</u> | 0.915142                 | <u>53</u> | <u>5</u> | 0.909272                 | <u>581</u> | 0.902875                 | <u>623</u> | 0.89864                  |
| <u>488</u> | 0.915088                 | <u>53</u> | <u>6</u> | 0.909163                 | <u>582</u> | 0.902875                 | <u>624</u> | 0.898527                 |
| <u>489</u> | 0.91498                  | <u>53</u> |          | 0.908945                 | <u>583</u> | 0.902765                 | <u>625</u> | 0.898414                 |
| <u>493</u> | <u>0.914926</u>          | <u>53</u> | <u>8</u> | 0.908836                 | <u>584</u> | 0.902655                 | <u>626</u> | 0.898414                 |

| t          | <u>S<sub>TX</sub>(t)</u> | +          | <u>S<sub>TX</sub>(t)</u> |   | t          | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|------------|--------------------------|---|------------|--------------------------|------------|--------------------------|
| 627        | 0.898187                 | 669        | 0.893228                 |   | 711        | 0.887613                 | 753        | 0.882092                 |
| 628        | 0.898017                 | 670        | 0.893052                 | - | 712        | 0.887309                 | 754        | 0.882029                 |
| 629        | 0.897903                 | 671        | 0.892935                 | - | 713        | 0.887188                 | 755        | 0.881902                 |
| 630        | 0.89779                  | 672        | 0.892641                 | - | 714        | 0.887188                 | 756        | 0.881839                 |
| 631        | 0.897562                 | 673        | 0.892641                 | - | 715        | 0.887005                 | 757        | 0.881713                 |
| 632        | 0.897505                 | 674        | 0.892523                 | • | 716        | 0.886883                 | <u>758</u> | 0.88165                  |
| 633        | 0.897448                 | 675        | 0.892405                 | • | 717        | 0.886883                 | 759        | 0.881586                 |
| 634        | 0.897277                 | 676        | 0.892346                 | • | 718        | 0.886883                 | 760        | 0.881333                 |
| 635        | 0.897163                 | 677        | 0.89211                  | - | 719        | 0.886821                 | 761        | 0.881142                 |
| 636        | 0.896992                 | 678        | 0.892051                 | - | 720        | 0.886821                 | 762        | 0.881015                 |
| 637        | 0.896935                 | 679        | 0.891874                 | • | 721        | 0.886821                 | 763        | 0.880888                 |
| 638        | 0.896878                 | 680        | 0.891756                 | • | 722        | 0.886637                 | 764        | 0.880825                 |
| 639        | 0.89682                  | <u>681</u> | 0.891519                 | - | 723        | 0.886515                 | 765        | 0.880761                 |
| 640        | 0.89682                  | 682        | 0.89146                  | - | 724        | 0.886453                 | 766        | 0.880634                 |
| 641        | 0.896591                 | <u>683</u> | 0.89146                  | • | 725        | 0.886207                 | 767        | 0.880315                 |
| 642        | 0.896534                 | <u>684</u> | 0.891341                 | • | 726        | 0.886146                 | <u>768</u> | 0.880187                 |
| 643        | 0.896477                 | <u>685</u> | 0.891162                 | • | <u>727</u> | 0.886084                 | <u>769</u> | 0.880187                 |
| 644        | 0.896247                 | <u>686</u> | 0.890805                 |   | 728        | 0.886084                 | <u>770</u> | 0.88006                  |
| <u>645</u> | 0.896075                 | <u>687</u> | 0.890567                 |   | <u>729</u> | 0.886022                 | <u>771</u> | 0.879932                 |
| <u>646</u> | 0.895845                 | <u>688</u> | 0.890507                 |   | <u>730</u> | 0.885961                 | <u>772</u> | 0.879676                 |
| <u>647</u> | 0.895729                 | <u>689</u> | 0.890448                 |   | <u>731</u> | <u>0.885899</u>          | <u>773</u> | 0.87942                  |
| <u>648</u> | 0.895556                 | <u>690</u> | 0.890448                 |   | <u>732</u> | <u>0.885775</u>          | <u>774</u> | <u>0.879356</u>          |
| <u>649</u> | 0.895441                 | <u>691</u> | 0.890328                 |   | <u>733</u> | 0.885528                 | <u>775</u> | 0.879292                 |
| <u>650</u> | 0.895268                 | <u>692</u> | 0.890268                 |   | <u>734</u> | 0.885528                 | <u>776</u> | 0.8791                   |
| <u>651</u> | 0.89521                  | <u>693</u> | 0.890149                 | _ | <u>735</u> | 0.885404                 | <u>777</u> | 0.878971                 |
| <u>652</u> | 0.895152                 | <u>694</u> | 0.890089                 | • | <u>736</u> | <u>0.885404</u>          | <u>778</u> | 0.878779                 |
| <u>653</u> | 0.895152                 | <u>695</u> | 0.890089                 |   | <u>737</u> | 0.885032                 | <u>779</u> | <u>0.878586</u>          |
| <u>654</u> | 0.894978                 | <u>696</u> | <u>0.889669</u>          | - | <u>738</u> | <u>0.884845</u>          | <u>780</u> | <u>0.878457</u>          |
| <u>655</u> | 0.894746                 | <u>697</u> | 0.889548                 |   | <u>739</u> | <u>0.884721</u>          | <u>781</u> | 0.878264                 |
| <u>656</u> | 0.894688                 | <u>698</u> | 0.889368                 |   | <u>740</u> | 0.884597                 | <u>782</u> | 0.878199                 |
| <u>657</u> | 0.894688                 | <u>699</u> | 0.889187                 | • | <u>741</u> | 0.884597                 | <u>783</u> | 0.878199                 |
| <u>658</u> | 0.894572                 | <u>700</u> | 0.889067                 | - | <u>742</u> | <u>0.884285</u>          | <u>784</u> | <u>0.87807</u>           |
| <u>659</u> | <u>0.894514</u>          | <u>701</u> | 0.888946                 | • | <u>743</u> | <u>0.884035</u>          | <u>785</u> | <u>0.87794</u>           |
| <u>660</u> | 0.894455                 | <u>702</u> | 0.888946                 | - | <u>744</u> | <u>0.88366</u>           | <u>786</u> | 0.877811                 |
| <u>661</u> | 0.894222                 | <u>703</u> | <u>0.888825</u>          |   | <u>745</u> | <u>0.883472</u>          | <u>787</u> | <u>0.877811</u>          |
| <u>662</u> | 0.893988                 | 704        | 0.888705                 | • | 746        | 0.88316                  | <u>788</u> | 0.877681                 |
| <u>663</u> | 0.893872                 | <u>705</u> | 0.888584                 | • | 747        | 0.883097                 | <u>789</u> | 0.877616                 |
| <u>664</u> | 0.893638                 | <u>706</u> | 0.888341                 |   | 748        | 0.882721                 | <u>790</u> | 0.877551                 |
| 665        | 0.893579                 | <u>707</u> | 0.88816                  |   | <u>749</u> | 0.882532                 | <u>791</u> | 0.877551                 |
| 666        | 0.893404                 | 708        | 0.888038                 |   | <u>750</u> | 0.88247                  | 792        | 0.877291                 |
| 667        | 0.893345                 | <u>709</u> | 0.887856                 | • | <u>751</u> | 0.882407                 | <u>793</u> | 0.877226                 |
| <u>668</u> | 0.893287                 | 710        | 0.887735                 |   | <u>752</u> | 0.882344                 | <u>794</u> | <u>0.877161</u>          |

| <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | t          | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> | <u>t</u>   | <u>S<sub>TX</sub>(t)</u> |
|------------|--------------------------|------------|--------------------------|------------|--------------------------|------------|--------------------------|
| 795        | 0.877031                 | 837        | 0.870775                 | 879        | 0.865397                 | 921        | 0.860785                 |
| 796        | 0.876835                 | 838        | 0.870707                 | 880        | 0.865397                 | 922        | 0.860712                 |
| 797        | 0.876639                 | 839        | 0.870435                 | 881        | 0.865186                 | 923        | 0.860712                 |
| 798        | 0.876443                 | 840        | 0.870367                 | 882        | 0.865044                 | 924        | 0.860492                 |
| 799        | 0.876443                 | 841        | 0.870231                 | 883        | 0.865044                 | 925        | 0.860345                 |
| 800        | 0.876312                 | 842        | 0.869755                 | <u>884</u> | 0.864974                 | <u>926</u> | 0.860197                 |
| <u>801</u> | 0.876312                 | <u>843</u> | 0.869619                 | <u>885</u> | 0.864903                 | <u>927</u> | 0.860124                 |
| <u>802</u> | 0.876246                 | <u>844</u> | 0.869482                 | <u>886</u> | 0.864832                 | <u>928</u> | 0.859976                 |
| <u>803</u> | <u>0.876115</u>          | <u>845</u> | 0.869414                 | <u>887</u> | <u>0.86469</u>           | <u>929</u> | <u>0.859828</u>          |
| <u>804</u> | <u>0.876049</u>          | <u>846</u> | 0.869209                 | <u>888</u> | <u>0.864619</u>          | <u>930</u> | 0.859828                 |
| <u>805</u> | 0.875918                 | <u>847</u> | 0.869141                 | <u>889</u> | <u>0.864619</u>          | <u>931</u> | 0.85968                  |
| <u>806</u> | 0.875786                 | <u>848</u> | 0.868936                 | <u>890</u> | 0.864477                 | <u>932</u> | 0.859606                 |
| <u>807</u> | 0.875654                 | <u>849</u> | 0.868799                 | <u>891</u> | 0.864335                 | <u>933</u> | 0.859458                 |
| <u>808</u> | 0.875522                 | <u>850</u> | 0.868593                 | <u>892</u> | 0.864335                 | <u>934</u> | 0.859384                 |
| <u>809</u> | 0.87539                  | <u>851</u> | 0.868456                 | <u>893</u> | 0.864192                 | <u>935</u> | 0.859384                 |
| <u>810</u> | 0.875192                 | <u>852</u> | 0.868319                 | <u>894</u> | 0.864121                 | <u>936</u> | 0.859235                 |
| <u>811</u> | 0.874795                 | <u>853</u> | 0.86825                  | <u>895</u> | 0.864049                 | <u>937</u> | 0.859012                 |
| <u>812</u> | <u>0.87453</u>           | <u>854</u> | 0.868112                 | <u>896</u> | 0.863978                 | <u>938</u> | 0.859012                 |
| <u>813</u> | 0.874398                 | <u>855</u> | 0.868112                 | <u>897</u> | 0.863978                 | <u>939</u> | 0.858863                 |
| <u>814</u> | 0.874332                 | <u>856</u> | 0.867768                 | <u>898</u> | 0.863978                 | <u>940</u> | 0.858863                 |
| <u>815</u> | 0.874265                 | <u>857</u> | 0.867768                 | <u>899</u> | 0.863978                 | <u>941</u> | 0.858714                 |
| <u>816</u> | 0.874265                 | <u>858</u> | 0.867768                 | <u>900</u> | 0.863691                 | <u>942</u> | 0.85849                  |
| <u>817</u> | 0.874133                 | <u>859</u> | 0.867561                 | <u>901</u> | 0.863691                 | <u>943</u> | <u>0.85849</u>           |
| <u>818</u> | 0.873933                 | <u>860</u> | 0.867422                 | <u>902</u> | 0.863691                 | <u>944</u> | 0.858266                 |
| <u>819</u> | 0.873866                 | <u>861</u> | 0.867353                 | <u>903</u> | 0.863619                 | <u>945</u> | 0.858191                 |
| <u>820</u> | <u>0.8736</u>            | <u>862</u> | 0.867215                 | <u>904</u> | 0.863474                 | <u>946</u> | 0.857966                 |
| <u>821</u> | <u>0.8734</u>            | <u>863</u> | 0.867215                 | <u>905</u> | 0.863402                 | <u>947</u> | 0.857891                 |
| <u>822</u> | <u>0.8734</u>            | <u>864</u> | 0.867215                 | <u>906</u> | 0.86333                  | <u>948</u> | 0.857665                 |
| <u>823</u> | 0.873199                 | <u>865</u> | i                        | <u>907</u> | 0.863186                 | <u>949</u> | <u>0.85759</u>           |
| <u>824</u> | <u>0.873066</u>          | <u>866</u> | 0.866937                 | <u>908</u> | 0.862896                 | <u>950</u> | <u>0.85759</u>           |
| <u>825</u> | <u>0.872865</u>          | <u>867</u> | <u>0.866867</u>          | <u>909</u> | <u>0.862607</u>          | <u>951</u> | <u>0.85744</u>           |
| <u>826</u> | <u>0.872664</u>          | <u>868</u> | 0.866797                 | <u>910</u> | 0.862317                 | <u>952</u> | <u>0.85744</u>           |
| <u>827</u> | <u>0.872462</u>          | <u>869</u> | <u>0.866728</u>          | <u>911</u> | <u>0.8621</u>            | <u>953</u> | <u>0.857364</u>          |
| <u>828</u> | 0.872395                 | <u>870</u> | 0.866588                 | <u>912</u> | <u>0.862027</u>          | <u>954</u> | <u>0.857063</u>          |
| <u>829</u> | <u>0.872261</u>          | <u>871</u> | 0.866518                 | <u>913</u> | <u>0.862027</u>          | <u>955</u> | <u>0.856987</u>          |
| 830        | 0.872193                 | <u>872</u> | 0.866518                 | 914        | 0.861881                 | <u>956</u> | 0.85676                  |
| <u>831</u> | 0.872059                 | <u>873</u> | 0.866379                 | <u>915</u> | 0.861809                 | <u>957</u> | 0.856685                 |
| 832        | 0.871856                 | <u>874</u> | 0.866169                 | <u>916</u> | 0.86159                  | <u>958</u> | 0.856305                 |
| 833        | 0.871519                 | <u>875</u> | 0.865889                 | <u>917</u> | 0.861517                 | <u>959</u> | 0.856229                 |
| 834        | 0.871384                 | <u>876</u> | 0.865748                 | 918        | 0.861444                 | <u>960</u> | 0.856229                 |
| 835        | 0.871249                 | <u>877</u> | 0.865608                 | <u>919</u> | 0.861078                 | <u>961</u> | 0.856153                 |
| <u>836</u> | <u>0.871046</u>          | <u>878</u> | 0.865467                 | <u>920</u> | 0.861078                 | <u>962</u> | 0.856077                 |

| t           | <u>S<sub>TX</sub>(t)</u> | t           | <u>S<sub>TX</sub>(t)</u> | ĺ | t           | <u>S<sub>TX</sub>(t)</u> | t           | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|-------------|--------------------------|---|-------------|--------------------------|-------------|--------------------------|
| 963         | 0.855772                 | 1005        | 0.851336                 |   | 1047        | 0.846714                 | 1089        | 0.841907                 |
| 964         | 0.855619                 | 1006        | 0.851257                 |   | 1048        | 0.846549                 | 1090        | 0.841907                 |
| 965         | 0.855619                 | 1007        | 0.851257                 |   | 1049        | 0.846301                 | 1091        | 0.841821                 |
| 966         | 0.855543                 | 1008        | 0.851098                 |   | 1050        | 0.84597                  | 1092        | 0.841734                 |
| 967         | 0.855313                 | 1009        | 0.851018                 |   | 1051        | 0.845804                 | 1093        | 0.841561                 |
| 968         | 0.855313                 | 1010        | 0.851018                 |   | 1052        | 0.845638                 | 1094        | 0.841389                 |
| 969         | 0.85516                  | 1011        | 0.851018                 |   | 1053        | 0.845389                 | 1095        | 0.841129                 |
| 970         | 0.855083                 | 1012        | 0.850858                 |   | 1054        | 0.845389                 | 1096        | 0.841042                 |
| 971         | 0.85493                  | 1013        | 0.850778                 |   | 1055        | 0.845389                 | 1097        | 0.840956                 |
| 972         | 0.854699                 | 1014        | 0.850778                 |   | 1056        | 0.845222                 | 1098        | 0.840869                 |
| 973         | 0.854622                 | 1015        | 0.850778                 |   | 1057        | 0.845138                 | 1099        | 0.840695                 |
| 974         | 0.854622                 | 1016        | 0.850618                 |   | 1058        | 0.845138                 | 1100        | 0.840695                 |
| 975         | 0.854545                 | 1017        | 0.850538                 |   | 1059        | 0.845138                 | 1101        | 0.840608                 |
| 976         | 0.854468                 | 1018        | 0.850217                 |   | 1060        | 0.844971                 | 1102        | 0.840434                 |
| 977         | 0.854237                 | 1019        | 0.849895                 |   | 1061        | 0.844971                 | 1103        | 0.840259                 |
| <u>978</u>  | 0.854159                 | 1020        | 0.849895                 |   | 1062        | 0.844887                 | 1104        | 0.839735                 |
| <u>979</u>  | 0.854159                 | 1021        | 0.849895                 |   | 1063        | 0.844887                 | <u>1105</u> | 0.839648                 |
| <u>980</u>  | 0.854082                 | <u>1022</u> | 0.849815                 |   | <u>1064</u> | 0.844719                 | <u>1106</u> | 0.839473                 |
| <u>981</u>  | 0.854005                 | <u>1023</u> | 0.849492                 |   | <u>1065</u> | <u>0.844635</u>          | <u>1107</u> | 0.839385                 |
| <u>982</u>  | 0.853927                 | <u>1024</u> | 0.849492                 |   | <u>1066</u> | <u>0.844635</u>          | <u>1108</u> | 0.839122                 |
| <u>983</u>  | 0.853694                 | <u>1025</u> | 0.849492                 |   | <u>1067</u> | 0.84455                  | <u>1109</u> | 0.839034                 |
| <u>984</u>  | 0.853616                 | <u>1026</u> | 0.849492                 |   | <u>1068</u> | <u>0.844466</u>          | <u>1110</u> | 0.838946                 |
| <u>985</u>  | 0.853539                 | <u>1027</u> | 0.84933                  |   | <u>1069</u> | 0.844466                 | <u>1111</u> | 0.838946                 |
| <u>986</u>  | 0.853539                 | <u>1028</u> | <u>0.84933</u>           |   | <u>1070</u> | 0.844128                 | <u>1112</u> | 0.838858                 |
| <u>987</u>  | 0.853383                 | <u>1029</u> | 0.84933                  |   | <u>1071</u> | 0.844044                 | <u>1113</u> | 0.838858                 |
| <u>988</u>  | 0.853305                 | <u>1030</u> | 0.849249                 |   | <u>1072</u> | 0.844044                 | <u>1114</u> | 0.838682                 |
| <u>989</u>  | 0.853149                 | <u>1031</u> | 0.849086                 |   | <u>1073</u> | <u>0.843959</u>          | <u>1115</u> | 0.838505                 |
| <u>990</u>  | 0.853071                 | <u>1032</u> | 0.848842                 |   | <u>1074</u> | <u>0.843959</u>          | <u>1116</u> | 0.838417                 |
| <u>991</u>  | 0.852914                 | <u>1033</u> | 0.848679                 |   | <u>1075</u> | 0.843789                 | <u>1117</u> | 0.838328                 |
| <u>992</u>  | 0.852836                 | <u>1034</u> | 0.848598                 |   | <u>1076</u> | 0.84362                  | <u>1118</u> | 0.838151                 |
| <u>993</u>  | 0.852836                 | <u>1035</u> | 0.848353                 |   | <u>1077</u> | 0.84362                  | <u>1119</u> | 0.838151                 |
| <u>994</u>  | 0.852758                 | <u>1036</u> | 0.848109                 |   | <u>1078</u> | 0.843535                 | <u>1120</u> | 0.837973                 |
| <u>995</u>  | <u>0.852679</u>          | <u>1037</u> | 0.848109                 |   | <u>1079</u> | 0.843364                 | <u>1121</u> | 0.837795                 |
| <u>996</u>  | <u>0.852601</u>          | <u>1038</u> | 0.847782                 |   | <u>1080</u> | 0.843194                 | <u>1122</u> | 0.837795                 |
| <u>997</u>  | <u>0.852601</u>          | <u>1039</u> | <u>0.847619</u>          |   | <u>1081</u> | 0.843023                 | <u>1123</u> | 0.837706                 |
| 998         | 0.852286                 | <u>1040</u> | 0.847619                 |   | <u>1082</u> | 0.843023                 | <u>1124</u> | 0.837706                 |
| 999         | 0.852049                 | <u>1041</u> | 0.847455                 |   | <u>1083</u> | 0.843023                 | <u>1125</u> | 0.837706                 |
| <u>1000</u> | 0.852049                 | <u>1042</u> | 0.847373                 |   | <u>1084</u> | 0.842851                 | <u>1126</u> | 0.837527                 |
| <u>1001</u> | 0.852049                 | <u>1043</u> | <u>0.84729</u>           |   | <u>1085</u> | 0.842508                 | <u>1127</u> | 0.837437                 |
| <u>1002</u> | 0.851812                 | <u>1044</u> | 0.847126                 |   | <u>1086</u> | 0.842337                 | <u>1128</u> | 0.837437                 |
| <u>1003</u> | 0.851495                 | <u>1045</u> | 0.846961                 |   | <u>1087</u> | 0.842251                 | <u>1129</u> | 0.837257                 |
| <u>1004</u> | <u>0.851336</u>          | <u>1046</u> | <u>0.846879</u>          |   | <u>1088</u> | 0.841993                 | <u>1130</u> | 0.836987                 |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | S <sub>TX</sub> (t) |
|-------------|--------------------------|-------------|--------------------------|-------------|--------------------------|-------------|---------------------|
| <u>1131</u> | 0.836896                 | 1173        | 0.830997                 | 1215        | 0.825487                 | 1257        | 0.82022             |
| <u>1132</u> | 0.836806                 | <u>1174</u> | 0.830997                 | 1216        | 0.825487                 | <u>1258</u> | 0.82022             |
| 1133        | 0.836806                 | 1175        | 0.830808                 | 1217        | 0.825487                 | 1259        | 0.820116            |
| 1134        | 0.836535                 | 1176        | 0.830524                 | 1218        | 0.825387                 | 1260        | 0.819804            |
| 1135        | 0.836263                 | 1177        | 0.830524                 | 1219        | 0.825288                 | 1261        | 0.819804            |
| 1136        | 0.835901                 | 1178        | 0.830429                 | 1220        | 0.824991                 | 1262        | 0.8197              |
| 1137        | 0.835719                 | 1179        | 0.830144                 | 1221        | 0.824891                 | 1263        | 0.819595            |
| <u>1138</u> | 0.835719                 | 1180        | 0.830049                 | 1222        | 0.824891                 | <u>1264</u> | 0.819387            |
| <u>1139</u> | 0.835628                 | <u>1181</u> | 0.830049                 | 1223        | 0.824891                 | <u>1265</u> | 0.819387            |
| <u>1140</u> | 0.835537                 | <u>1182</u> | 0.829858                 | 1224        | 0.824692                 | <u>1266</u> | 0.819177            |
| <u>1141</u> | 0.835446                 | <u>1183</u> | 0.829763                 | 1225        | 0.824392                 | <u>1267</u> | 0.818968            |
| <u>1142</u> | 0.835082                 | <u>1184</u> | 0.829763                 | 1226        | 0.824392                 | <u>1268</u> | 0.818863            |
| <u>1143</u> | 0.835082                 | <u>1185</u> | 0.829667                 | <u>1227</u> | 0.824292                 | <u>1269</u> | 0.818653            |
| <u>1144</u> | 0.834899                 | <u>1186</u> | 0.829571                 | <u>1228</u> | 0.823992                 | <u>1270</u> | 0.818548            |
| <u>1145</u> | 0.834899                 | <u>1187</u> | 0.829379                 | <u>1229</u> | 0.823791                 | <u>1271</u> | 0.818442            |
| <u>1146</u> | 0.834532                 | <u>1188</u> | 0.829187                 | <u>1230</u> | <u>0.823791</u>          | <u>1272</u> | 0.818126            |
| <u>1147</u> | 0.834532                 | <u>1189</u> | 0.82861                  | <u>1231</u> | 0.823791                 | <u>1273</u> | 0.818126            |
| <u>1148</u> | <u>0.834256</u>          | <u>1190</u> | 0.82861                  | <u>1232</u> | 0.823791                 | <u>1274</u> | <u>0.818021</u>     |
| <u>1149</u> | <u>0.834256</u>          | <u>1191</u> | 0.828417                 | <u>1233</u> | <u>0.82369</u>           | <u>1275</u> | <u>0.817809</u>     |
| <u>1150</u> | 0.834072                 | <u>1192</u> | 0.828224                 | <u>1234</u> | 0.823489                 | <u>1276</u> | 0.817598            |
| <u>1151</u> | 0.834072                 | <u>1193</u> | 0.827837                 | <u>1235</u> | 0.823187                 | <u>1277</u> | 0.817492            |
| <u>1152</u> | 0.834072                 | <u>1194</u> | 0.827643                 | <u>1236</u> | 0.822884                 | <u>1278</u> | 0.817386            |
| <u>1153</u> | 0.833795                 | <u>1195</u> | 0.827546                 | <u>1237</u> | 0.822884                 | <u>1279</u> | 0.817173            |
| <u>1154</u> | <u>0.83361</u>           | <u>1196</u> | 0.827546                 | <u>1238</u> | 0.822884                 | <u>1280</u> | 0.817067            |
| <u>1155</u> | 0.833518                 | <u>1197</u> | 0.827449                 | <u>1239</u> | 0.822884                 | <u>1281</u> | 0.817067            |
| <u>1156</u> | 0.833147                 | <u>1198</u> | 0.827449                 | <u>1240</u> | 0.822681                 | <u>1282</u> | 0.817067            |
| <u>1157</u> | 0.833147                 | <u>1199</u> | 0.827254                 | <u>1241</u> | 0.822579                 | <u>1283</u> | 0.817067            |
| <u>1158</u> | 0.833055                 | <u>1200</u> | 0.827059                 | <u>1242</u> | 0.822274                 | <u>1284</u> | 0.816854            |
| <u>1159</u> | 0.832869                 | <u>1201</u> | 0.826961                 | <u>1243</u> | 0.822172                 | <u>1285</u> | <u>0.81664</u>      |
| <u>1160</u> | 0.832683                 | <u>1202</u> | 0.826863                 | <u>1244</u> | 0.82207                  | <u>1286</u> | <u>0.81664</u>      |
| <u>1161</u> | 0.832683                 | <u>1203</u> | <u>0.826765</u>          | <u>1245</u> | 0.82207                  | <u>1287</u> | <u>0.81664</u>      |
| <u>1162</u> | <u>0.83231</u>           | <u>1204</u> | 0.826569                 | <u>1246</u> | 0.821968                 | <u>1288</u> | <u>0.816426</u>     |
| <u>1163</u> | 0.832217                 | <u>1205</u> | 0.826373                 | <u>1247</u> | 0.821968                 | <u>1289</u> | <u>0.816426</u>     |
| <u>1164</u> | 0.832124                 | <u>1206</u> | 0.826373                 | <u>1248</u> | 0.821456                 | <u>1290</u> | 0.816211            |
| <u>1165</u> | 0.832124                 | <u>1207</u> | 0.826373                 | <u>1249</u> | 0.821149                 | <u>1291</u> | <u>0.816103</u>     |
| <u>1166</u> | 0.831843                 | <u>1208</u> | 0.826373                 | <u>1250</u> | 0.821149                 | <u>1292</u> | 0.816103            |
| <u>1167</u> | 0.831655                 | <u>1209</u> | 0.826373                 | <u>1251</u> | 0.821149                 | <u>1293</u> | 0.815887            |
| <u>1168</u> | 0.831561                 | <u>1210</u> | 0.826275                 | <u>1252</u> | 0.821149                 | <u>1294</u> | 0.81567             |
| <u>1169</u> | 0.831186                 | <u>1211</u> | <u>0.826078</u>          | <u>1253</u> | <u>0.82084</u>           | <u>1295</u> | 0.815562            |
| <u>1170</u> | 0.831092                 | <u>1212</u> | 0.825782                 | <u>1254</u> | 0.820634                 | <u>1296</u> | 0.815562            |
| <u>1171</u> | 0.830997                 | <u>1213</u> | 0.825585                 | <u>1255</u> | 0.82053                  | <u>1297</u> | 0.815562            |
| <u>1172</u> | 0.830997                 | <u>1214</u> | <u>0.825487</u>          | <u>1256</u> | 0.82022                  | <u>1298</u> | 0.815453            |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |           | <u>t</u>  | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|-------------|--------------------------|-----------|-----------|--------------------------|-------------|--------------------------|
| 1299        | 0.815236                 | 1342        | 0.811217                 | <u>13</u> | 84        | 0.806427                 | <u>1426</u> | 0.801015                 |
| 1300        | 0.815236                 | 1343        | 0.810988                 | <u>13</u> | <u>85</u> | 0.806187                 | <u>1427</u> | 0.800636                 |
| 1301        | 0.815236                 | 1344        | 0.810873                 | 13        | 86        | 0.806067                 | 1428        | 0.800256                 |
| 1302        | 0.815236                 | 1345        | 0.810528                 | <u>13</u> | 87        | 0.805826                 | 1429        | 0.800003                 |
| 1303        | 0.815236                 | 1346        | 0.810298                 | 13        | 88        | 0.805586                 | 1430        | 0.800003                 |
| 1304        | 0.815236                 | 1347        | 0.810183                 | <u>13</u> | 89        | 0.805586                 | <u>1431</u> | 0.800003                 |
| <u>1305</u> | 0.814798                 | <u>1348</u> | 0.810068                 | <u>13</u> | 90        | 0.805344                 | <u>1432</u> | 0.800003                 |
| <u>1306</u> | 0.814798                 | <u>1349</u> | 0.809953                 | <u>13</u> | 91        | 0.805223                 | <u>1433</u> | 0.800003                 |
| <u>1307</u> | 0.814579                 | <u>1350</u> | 0.809722                 | <u>13</u> | 92        | 0.805223                 | <u>1434</u> | 0.799875                 |
| <u>1308</u> | 0.814359                 | <u>1351</u> | 0.809722                 | <u>13</u> | 93        | <u>0.805102</u>          | <u>1435</u> | 0.79962                  |
| <u>1309</u> | 0.814359                 | <u>1352</u> | 0.809722                 | <u>13</u> | 94        | <u>0.805102</u>          | <u>1436</u> | 0.799493                 |
| <u>1310</u> | 0.814029                 | <u>1353</u> | 0.809374                 | <u>13</u> | 95        | <u>0.805102</u>          | <u>1437</u> | <u>0.799365</u>          |
| <u>1311</u> | 0.814029                 | <u>1354</u> | 0.809258                 | <u>13</u> | <u>96</u> | <u>0.804981</u>          | <u>1438</u> | <u>0.799365</u>          |
| <u>1312</u> | 0.813809                 | <u>1355</u> | 0.809142                 | <u>13</u> | <u>97</u> | 0.804737                 | <u>1439</u> | <u>0.799365</u>          |
| <u>1313</u> | 0.813809                 | <u>1356</u> | 0.809025                 | <u>13</u> | <u>98</u> | 0.804615                 | <u>1440</u> | <u>0.799365</u>          |
| <u>1314</u> | 0.813809                 | <u>1357</u> | 0.808909                 | <u>13</u> | <u>99</u> | 0.804494                 | <u>1441</u> | <u>0.799365</u>          |
| <u>1315</u> | 0.813809                 | <u>1358</u> | 0.808793                 | <u>14</u> | 00        | 0.804494                 | <u>1442</u> | 0.799108                 |
| <u>1316</u> | 0.813698                 | <u>1359</u> | 0.808676                 | <u>14</u> | 01        | 0.804371                 | <u>1443</u> | 0.799108                 |
| <u>1317</u> | 0.813587                 | <u>1360</u> | 0.808676                 | <u>14</u> | 02        | 0.804249                 | <u>1444</u> | 0.799108                 |
| <u>1318</u> | 0.813365                 | <u>1361</u> | 0.808676                 | <u>14</u> | 03        | 0.804249                 | <u>1445</u> | 0.798849                 |
| <u>1319</u> | 0.813365                 | <u>1362</u> | 0.808442                 | <u>14</u> | 04        | 0.804126                 | <u>1446</u> | 0.79872                  |
| <u>1320</u> | 0.813142                 | <u>1363</u> | 0.80809                  | <u>14</u> | <u>05</u> | 0.803635                 | <u>1447</u> | 0.79872                  |
| <u>1321</u> | 0.813142                 | <u>1364</u> | 0.80809                  | <u>14</u> | <u>06</u> | 0.803635                 | <u>1448</u> | 0.798332                 |
| <u>1322</u> | 0.813142                 | <u>1365</u> | 0.807972                 | <u>14</u> | <u>07</u> | 0.803635                 | <u>1449</u> | 0.798332                 |
| <u>1323</u> | 0.813142                 | <u>1366</u> | 0.807855                 | <u>14</u> | <u>80</u> | 0.803512                 | <u>1450</u> | 0.798072                 |
| <u>1324</u> | 0.812918                 | <u>1367</u> | 0.807855                 | <u>14</u> | <u>09</u> | <u>0.803265</u>          | <u>1451</u> | 0.797942                 |
| <u>1325</u> | 0.812918                 | <u>1368</u> | 0.807737                 | <u>14</u> | <u>10</u> | 0.803265                 | <u>1452</u> | 0.797682                 |
| <u>1326</u> | <u>0.812806</u>          | <u>1369</u> | 0.807737                 | <u>14</u> | <u>11</u> | <u>0.803141</u>          | <u>1453</u> | 0.797682                 |
| <u>1327</u> | 0.812806                 | <u>1370</u> | 0.807737                 | <u>14</u> | <u>12</u> | <u>0.803141</u>          | <u>1454</u> | <u>0.79729</u>           |
| <u>1328</u> | 0.812581                 | <u>1371</u> | 0.807618                 | <u>14</u> | <u>13</u> | 0.803017                 | <u>1455</u> | <u>0.79729</u>           |
| <u>1329</u> | 0.812468                 | <u>1372</u> | 0.807618                 | <u>14</u> | <u>14</u> | <u>0.802893</u>          | <u>1456</u> | <u>0.796897</u>          |
| <u>1331</u> | 0.812356                 | <u>1373</u> | 0.807618                 | <u>14</u> | <u>15</u> | <u>0.802395</u>          | <u>1457</u> | 0.796765                 |
| <u>1332</u> | 0.812356                 | <u>1374</u> | <u>0.8075</u>            | <u>14</u> | <u>16</u> | <u>0.802395</u>          | <u>1458</u> | 0.796634                 |
| <u>1333</u> | 0.812356                 | <u>1375</u> | 0.807143                 | <u>14</u> | <u>17</u> | 0.802145                 | <u>1459</u> | 0.796502                 |
| <u>1334</u> | 0.812243                 | <u>1376</u> | 0.807024                 | <u>14</u> | <u>18</u> | <u>0.801895</u>          | <u>1460</u> | <u>0.796502</u>          |
| <u>1335</u> | 0.812243                 | <u>1377</u> | 0.806905                 | <u>14</u> | <u>19</u> | 0.801895                 | <u>1461</u> | 0.796238                 |
| <u>1336</u> | 0.81213                  | <u>1378</u> | 0.806905                 | <u>14</u> | <u>20</u> | 0.801895                 | <u>1462</u> | 0.796238                 |
| <u>1337</u> | 0.811903                 | <u>1379</u> | 0.806905                 | <u>14</u> | <u>21</u> | 0.801644                 | <u>1463</u> | 0.796105                 |
| <u>1338</u> | 0.811903                 | <u>1380</u> | 0.806905                 | <u>14</u> | 22        | <u>0.801519</u>          | <u>1464</u> | <u>0.795708</u>          |
| <u>1339</u> | <u>0.811561</u>          | <u>1381</u> | 0.806786                 | <u>14</u> | 23        | 0.801141                 | <u>1465</u> | <u>0.795708</u>          |
| <u>1340</u> | 0.811446                 | <u>1382</u> | 0.806786                 | <u>14</u> | <u>24</u> | 0.801141                 | <u>1466</u> | <u>0.795441</u>          |
| <u>1341</u> | 0.811332                 | <u>1383</u> | 0.806546                 | <u>14</u> | <u>25</u> | <u>0.801141</u>          | <u>1467</u> | <u>0.795174</u>          |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |             | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> | <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|-------------|--------------------------|-------------|-------------|--------------------------|-------------|--------------------------|
| 1468        | 0.795174                 | 1510        | 0.790383                 | 15          | 553         | 0.785533                 | 1595        | 0.782887                 |
| 1469        | 0.795174                 | 1511        | 0.790241                 | 15          | 554         | 0.785381                 | 1596        | 0.782887                 |
| 1470        | 0.79504                  | 1512        | 0.790241                 | 15          | 555         | 0.785381                 | 1597        | 0.782887                 |
| 1471        | 0.794638                 | 1513        | 0.790098                 | 15          | 556         | 0.785076                 | 1598        | 0.782887                 |
| 1472        | 0.794503                 | 1514        | 0.790098                 | 15          | 557         | 0.785076                 | 1599        | 0.782887                 |
| 1473        | 0.794503                 | <u>1515</u> | 0.790098                 | 15          | 5 <u>58</u> | 0.784923                 | 1600        | 0.782887                 |
| 1474        | 0.794368                 | <u>1516</u> | 0.789813                 | 15          | 5 <u>59</u> | 0.784769                 | 1601        | 0.782887                 |
| <u>1475</u> | 0.794368                 | <u>1518</u> | 0.789813                 | <u>15</u>   | 560         | 0.784769                 | <u>1602</u> | 0.782887                 |
| <u>1476</u> | <u>0.794233</u>          | <u>1519</u> | <u>0.789813</u>          | <u>15</u>   | 5 <u>61</u> | <u>0.784769</u>          | <u>1603</u> | <u>0.782723</u>          |
| <u>1477</u> | 0.793827                 | <u>1520</u> | <u>0.789669</u>          | <u>15</u>   | <u> 562</u> | 0.784462                 | <u>1604</u> | 0.782723                 |
| <u>1478</u> | <u>0.793691</u>          | <u>1521</u> | <u>0.789525</u>          | <u>15</u>   | <u> 563</u> | 0.784308                 | <u>1605</u> | 0.782723                 |
| <u>1479</u> | 0.793419                 | <u>1522</u> | 0.789237                 | <u>15</u>   | <u> 564</u> | 0.784308                 | <u>1606</u> | 0.782559                 |
| <u>1480</u> | 0.793419                 | <u>1523</u> | 0.789237                 | <u>15</u>   | 5 <u>65</u> | 0.784153                 | <u>1607</u> | 0.782559                 |
| <u>1481</u> | 0.793147                 | <u>1524</u> | 0.789237                 | <u>15</u>   | <u> 566</u> | 0.784153                 | <u>1608</u> | 0.782559                 |
| <u>1482</u> | 0.79301                  | <u>1525</u> | 0.789092                 | <u>15</u>   | <u> 567</u> | 0.784153                 | <u>1609</u> | 0.782559                 |
| <u>1483</u> | 0.792737                 | <u>1526</u> | 0.788947                 | <u>15</u>   | <u> 568</u> | <u>0.784153</u>          | <u>1610</u> | 0.782559                 |
| <u>1484</u> | 0.792737                 | <u>1527</u> | 0.788947                 | <u>15</u>   | 5 <u>69</u> | <u>0.784153</u>          | <u>1611</u> | 0.782228                 |
| <u>1485</u> | 0.792737                 | <u>1528</u> | 0.788947                 | <u>15</u>   | 57 <u>0</u> | <u>0.784153</u>          | <u>1612</u> | 0.782228                 |
| <u>1486</u> | 0.792737                 | <u>1529</u> | <u>0.788654</u>          | <u>15</u>   | 57 <u>1</u> | <u>0.784153</u>          | <u>1613</u> | 0.782228                 |
| <u>1487</u> | 0.792464                 | <u>1530</u> | 0.788654                 | <u>15</u>   | 57 <u>2</u> | 0.783997                 | <u>1614</u> | 0.782228                 |
| <u>1488</u> | 0.792464                 | <u>1531</u> | 0.788361                 | <u>15</u>   | 57 <u>3</u> | 0.783997                 | <u>1615</u> | 0.781895                 |
| <u>1489</u> | 0.792464                 | <u>1532</u> | 0.788215                 | <u>15</u>   | 57 <u>4</u> | 0.783997                 | <u>1616</u> | 0.781895                 |
| <u>1490</u> | 0.792189                 | <u>1533</u> | 0.787921                 | <u>15</u>   | 57 <u>5</u> | 0.783997                 | <u>1617</u> | 0.781895                 |
| <u>1491</u> | 0.792052                 | <u>1534</u> | 0.787921                 | 15          | 57 <u>6</u> | 0.783839                 | <u>1618</u> | 0.781895                 |
| <u>1492</u> | <u>0.791776</u>          | <u>1535</u> | 0.787627                 | 15          | <u>577</u>  | 0.783682                 | <u>1619</u> | <u>0.781895</u>          |
| <u>1493</u> | <u>0.791776</u>          | <u>1536</u> | <u>0.787479</u>          | <u>15</u>   | 57 <u>8</u> | <u>0.783524</u>          | <u>1620</u> | <u>0.781895</u>          |
| <u>1494</u> | <u>0.791362</u>          | <u>1537</u> | <u>0.787479</u>          |             | 57 <u>9</u> | <u>0.783524</u>          | <u>1621</u> | <u>0.781895</u>          |
| <u>1495</u> | <u>0.791223</u>          | <u>1538</u> | <u>0.787479</u>          | <del></del> | 5 <u>80</u> | <u>0.783366</u>          | <u>1622</u> | <u>0.781726</u>          |
| <u>1496</u> | 0.791223                 | <u>1539</u> | 0.787479                 |             | 5 <u>81</u> | <u>0.783366</u>          |             | <u>0.781726</u>          |
| <u>1497</u> | <u>0.791084</u>          | <u>1540</u> | <u>0.787035</u>          |             | <u>582</u>  | <u>0.783366</u>          | <u>1624</u> | <u>0.781558</u>          |
| <u>1498</u> | <u>0.791084</u>          | <u>1541</u> | <u>0.787035</u>          |             | <u>583</u>  | <u>0.783207</u>          | <u>1625</u> | <u>0.781221</u>          |
| <u>1499</u> | <u>0.791084</u>          | <u>1542</u> | <u>0.787035</u>          |             | <u>584</u>  | <u>0.783207</u>          | <u>1626</u> | <u>0.781052</u>          |
| <u>1500</u> | <u>0.791084</u>          | <u>1543</u> | <u>0.787035</u>          |             | <u>585</u>  | <u>0.783047</u>          | <u>1627</u> | <u>0.781052</u>          |
| <u>1501</u> | 0.790945                 | <u>1544</u> | <u>0.787035</u>          |             | <u>586</u>  | <u>0.783047</u>          | <u>1628</u> | <u>0.780544</u>          |
| <u>1502</u> | <u>0.790805</u>          | <u>1545</u> | <u>0.786736</u>          |             | <u>587</u>  | <u>0.783047</u>          | <u>1629</u> | <u>0.780205</u>          |
| <u>1503</u> | <u>0.790665</u>          | <u>1546</u> | 0.786287                 |             | 5 <u>88</u> | 0.783047                 | <u>1630</u> | 0.780035                 |
| <u>1504</u> | 0.790665                 | <u>1547</u> | 0.786137                 |             | 5 <u>89</u> | 0.782887                 | 1631        | 0.780035                 |
| <u>1505</u> | 0.790524                 | <u>1548</u> | 0.786137                 |             | 5 <u>90</u> | 0.782887                 | 1632        | 0.780035                 |
| <u>1506</u> | 0.790524                 | <u>1549</u> | 0.785986                 |             | 5 <u>91</u> | 0.782887                 | 1633        | 0.780035                 |
| <u>1507</u> | 0.790524                 | <u>1550</u> | 0.785835                 |             | 5 <u>92</u> | 0.782887                 | 1634        | 0.780035                 |
| <u>1508</u> | 0.790524                 | <u>1551</u> | 0.785684                 |             | 5 <u>93</u> | 0.782887                 | 1635        | 0.780035                 |
| <u>1509</u> | 0.790524                 | <u>1552</u> | 0.785533                 | 15          | <u>594</u>  | <u>0.782887</u>          | <u>1636</u> | <u>0.780035</u>          |

|             | - 43                     |              | - ()     |             | - 11            |            | _              | - ()                     |
|-------------|--------------------------|--------------|----------|-------------|-----------------|------------|----------------|--------------------------|
| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |              |          | <u>t</u>    |                 |            | <u>t</u>       | <u>S<sub>TX</sub>(t)</u> |
| <u>1637</u> | <u>0.779691</u>          | <u>1680</u>  | +        | 1722        | <u>0.770505</u> | <u>176</u> |                | 0.763412                 |
| <u>1638</u> | <u>0.779691</u>          | <u>1681</u>  | 0.775931 | 1723        | <u>0.770304</u> | <u>176</u> |                | <u>0.763196</u>          |
| <u>1639</u> | <u>0.779691</u>          | <u>1682</u>  |          | <u>1724</u> |                 | <u>176</u> |                | 0.763196                 |
| <u>1640</u> | <u>0.779345</u>          | <u>1683</u>  |          | <u>1725</u> | <u>0.769699</u> | <u>176</u> |                | <u>0.763196</u>          |
| <u>1641</u> | 0.779172                 | <u>1684</u>  |          | <u>1726</u> | <u> </u>        | <u>176</u> |                | 0.763196                 |
| <u>1642</u> | <u>0.778825</u>          | <u>1685</u>  |          | <u>1727</u> | 0.769699        | <u>177</u> |                | 0.763196                 |
| <u>1643</u> | <u>0.778825</u>          | <u>1686</u>  | -        | <u>1728</u> |                 | <u>177</u> |                | 0.763196                 |
| <u>1644</u> | 0.778652                 | <u>1687</u>  | +        | <u>1730</u> | 0.769496        | <u>177</u> |                | 0.76276                  |
| <u>1645</u> | <u>0.778652</u>          | <u>1688</u>  | -        | <u>1731</u> | 0.769293        | <u>177</u> |                | 0.762542                 |
| <u>1646</u> | <u>0.778652</u>          | <u>1689</u>  |          | <u>1732</u> | <u>0.769293</u> | <u>177</u> |                | 0.762542                 |
| <u>1647</u> | 0.778652                 | <u>1690</u>  |          | <u>1733</u> | 0.769293        | <u>177</u> |                | 0.762323                 |
| <u>1648</u> | 0.778652                 | <u>1691</u>  |          | <u>1734</u> |                 | <u>177</u> |                | 0.761884                 |
| <u>1649</u> | 0.778652                 | <u>1692</u>  | 0.77462  | <u>1735</u> | 0.769088        | <u>177</u> | <u>'7</u>      | 0.761664                 |
| <u>1650</u> | 0.778652                 | <u>1693</u>  | 0.77462  | <u>1736</u> | 0.768883        | <u>177</u> | <u>′8</u>      | 0.761224                 |
| <u>1651</u> | 0.778475                 | <u>169</u> 4 | 0.77443  | <u>1737</u> | 0.768883        | <u>177</u> | <u> 19</u>     | 0.761003                 |
| <u>1652</u> | <u>0.778475</u>          | <u>1695</u>  | 0.774048 | <u>1738</u> | <u>0.768678</u> | <u>178</u> | <u> 30</u>     | 0.760782                 |
| <u>1653</u> | 0.778298                 | <u>1696</u>  | 0.774048 | <u>1739</u> | 0.768472        | <u>178</u> | <u>}1</u>      | 0.760782                 |
| <u>1654</u> | 0.777943                 | <u>1697</u>  | 0.773856 | <u>1740</u> | 0.768472        | <u>178</u> | <u>32</u>      | 0.760782                 |
| <u>1655</u> | 0.777943                 | <u>1698</u>  | 0.773664 | <u>1741</u> | 0.768472        | <u>178</u> | <u>33</u>      | 0.760337                 |
| <u>1656</u> | 0.777943                 | <u>1699</u>  | 0.773471 | <u>1742</u> | 0.768265        | <u>178</u> | <u> 34</u>     | 0.760337                 |
| <u>1658</u> | 0.777765                 | <u>1700</u>  | 0.773471 | <u>1743</u> | 0.768265        | <u>178</u> | <u>35</u>      | 0.760337                 |
| <u>1659</u> | 0.777765                 | <u>1701</u>  | 0.773471 | <u>1744</u> | <u>0.76785</u>  | <u>178</u> | <u> 36</u>     | 0.760337                 |
| <u>1660</u> | <u>0.777765</u>          | <u>1702</u>  | 0.773471 | <u>1745</u> | <u>0.76785</u>  | <u>178</u> | <u> 37</u>     | 0.760337                 |
| <u>1661</u> | 0.777765                 | <u>1703</u>  | 0.773277 | <u>1746</u> | 0.767434        | <u>178</u> | <u> 88</u>     | 0.759442                 |
| <u>1662</u> | 0.777765                 | <u>1704</u>  | 0.773277 | <u>1747</u> | 0.766599        | <u>178</u> | <u> 39</u>     | 0.759217                 |
| <u>1663</u> | 0.777765                 | <u>1705</u>  | 0.773083 | <u>1748</u> | 0.766599        | <u>179</u> | <u>)0</u>      | 0.759217                 |
| 1664        | 0.777765                 | 1706         | 0.773083 | 1749        | 0.766389        | 179        | <u>)1</u>      | 0.759217                 |
| 1665        | 0.777584                 | 1707         | 0.772692 | 1750        | 0.765758        | 179        | )2             | 0.759217                 |
| <u>1666</u> | 0.777584                 | <u>1708</u>  | 0.772497 | <u>1751</u> | 0.765758        | <u>179</u> | <del>)</del> 3 | 0.759217                 |
| <u>1667</u> | <u>0.777584</u>          | <u>1709</u>  | 0.772497 | <u>1752</u> | 0.765547        | <u>179</u> | <u>)4</u>      | 0.759217                 |
| <u>1668</u> | 0.777584                 | <u>1710</u>  | 0.772497 | <u>1753</u> | 0.765125        | <u>179</u> | ) <u>5</u>     | <u>0.758991</u>          |
| <u>1669</u> | <u>0.777584</u>          | <u>1711</u>  | 0.772497 | <u>1754</u> | 0.764913        | <u>179</u> | <u> 16</u>     | <u>0.758991</u>          |
| <u>1670</u> | <u>0.777402</u>          | <u>1712</u>  | 0.772497 | <u>1755</u> | 0.764913        | <u>179</u> | <u>)7</u>      | <u>0.758991</u>          |
| <u>1671</u> | 0.777402                 | <u>1713</u>  | 0.772497 | <u>1756</u> | <u>0.764701</u> | <u>179</u> | <del>)</del> 8 | 0.758991                 |
| <u>1672</u> | 0.777402                 | <u>171</u> 4 | 0.7723   | <u>1757</u> | 0.764701        | <u>179</u> | <del>)</del> 9 | 0.758762                 |
| 1673        | 0.777219                 | <u>1715</u>  | 0.7723   | 1758        | 0.764701        | <u>180</u> | )0             | 0.758533                 |
| <u>1674</u> | 0.777219                 | 1716         | 0.7723   | <u>1759</u> | 0.764701        | <u>180</u> | )1             | 0.758533                 |
| <u>1675</u> | 0.776668                 | <u>1717</u>  | 0.772101 | <u>1760</u> | 0.764487        | <u>180</u> | )2             | 0.758303                 |
| 1676        | 0.776668                 | 1718         | 0.771505 | 1761        | 0.764487        | 180        | )3             | 0.758303                 |
| 1677        | 0.776301                 | 1719         | 0.771505 | 1762        | 0.764487        | 180        | )4             | 0.758303                 |
| 1678        | 0.776116                 | <u>1720</u>  | 0.770906 | <u>1763</u> | 0.764487        | 180        | )5             | 0.758303                 |
| 1679        | 0.776116                 | <u>1721</u>  | 0.770906 | <u>1764</u> | 0.764057        | 180        | )6             | 0.758303                 |
|             | · — — —                  | . L <u></u>  | · — —    |             |                 |            |                |                          |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|
| <u>1807</u> | 0.758303                 |
| 1808        | 0.75807                  |
| 1809        | 0.757837                 |
| <u>1810</u> | 0.757837                 |
| 1811        | 0.757837                 |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|
| <u>1812</u> | 0.757602                 |
| <u>1813</u> | 0.757602                 |
| 1814        | 0.757602                 |
| 1815        | 0.757602                 |
| 1816        | 0.757602                 |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u>  |    |
|-------------|---------------------------|----|
| <u>1817</u> | 0.757602                  |    |
| <u>1818</u> | 0.757365                  |    |
| <u>1819</u> | 0.757365                  |    |
| 1820        | 0.757365                  |    |
| <u>1821</u> | <u>0.75688<b>\$</b></u> 1 | 45 |

| <u>t</u>    | <u>S<sub>TX</sub>(t)</u> |
|-------------|--------------------------|
| 1822        | 0.756888                 |
| <u>1823</u> | 0.756888                 |
| <u>1824</u> | 0.756409                 |
| <u>1825</u> | <u>0.756169</u>          |

11461147

1148

1149

### 21.2.C Values Used in the Calculation of Biological Disadvantages

### 21.2.C.1 Probability of Incompatible Lung Donors Based on Height

<u>Table 21-9 lists the proportion of incompatible donors based on the candidate's height and diagnosis group.</u>

115011511152

Table 21-9 Proportion of Incompatible Donors Based on Lung Height

| <u>Candidate</u><br><u>height (cm)</u> | Proportion for Candidates in Diagnosis Groups A and <u>C</u> | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--|--|--|--|
| 63 or less                             | <u>0.9949</u>  | <u>0.9949</u>  | <u>0.9949</u>  |
| <u>64</u>                              | <u>0.9916</u>  | <u>0.9949</u>  | <u>0.9949</u>  |
| <u>65</u>                              | <u>0.9916</u>  | <u>0.9949</u>  | <u>0.9949</u>  |
| <u>66</u>                              | <u>0.9899</u>  | <u>0.9949</u>  | <u>0.9949</u>  |
| <u>67</u>                              | <u>0.9882</u>  | 0.9949   | <u>0.9949</u>  |
| <u>68</u>                              | <u>0.9882</u>  | 0.9949   | <u>0.9949</u>  |
| <u>69</u>                              | <u>0.9882</u>  | <u>0.9916</u>  | <u>0.9949</u>  |
| <u>70</u>                              | <u>0.9882</u>  | <u>0.9916</u>  | <u>0.9949</u>  |
| <u>71</u>                              | <u>0.9866</u>  | <u>0.9882</u>  | <u>0.9916</u>  |
| <u>72</u>                              | <u>0.9866</u>  | <u>0.9882</u>  | <u>0.9916</u>  |
| <u>73</u>                              | <u>0.9849</u>  | <u>0.9882</u>  | <u>0.9899</u>  |
| <u>74</u>                              | <u>0.9849</u>  | <u>0.9882</u>  | <u>0.9882</u>  |
| <u>75</u>                              | <u>0.9849</u>  | <u>0.9882</u>  | <u>0.9882</u>  |
| <u>76</u>                              | <u>0.9866</u>  | <u>0.9866</u>  | <u>0.9882</u>  |
| <u>77</u>                              | 0.9849   | <u>0.9866</u>  | 0.9882   |
| <u>78</u>                              | <u>0.9849</u>  | 0.9849   | <u>0.9866</u>  |
| <u>79</u>                              | 0.9849   | 0.9849   | 0.9866   |
| <u>80</u>                              | 0.9849   | 0.9866   | 0.9849   |
| <u>81</u>                              | 0.9849   | <u>0.9866</u>  | 0.9849   |
| <u>82</u>                              | 0.9866   | 0.9849   | 0.9849   |
| <u>83</u>                              | <u>0.9866</u>  | <u>0.9849</u>  | <u>0.9849</u>  |



| Candidate<br>height (cm) | Proportion for Candidates in Diagnosis Groups A and C | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--------------------------|---|--|--|
| <u>84</u>                | <u>0.9882</u>   | <u>0.9849</u>  | 0.9833   |
| <u>85</u>                | <u>0.9882</u>   | <u>0.9849</u>  | <u>0.9849</u>  |
| <u>86</u>                | <u>0.9882</u>   | 0.9866   | 0.9849   |
| <u>87</u>                | <u>0.9849</u>   | 0.9866   | <u>0.9849</u>  |
| <u>88</u>                | <u>0.9849</u>   | 0.9882   | 0.9849   |
| <u>89</u>                | <u>0.9849</u>   | 0.9882   | <u>0.9849</u>  |
| <u>90</u>                | <u>0.9849</u>   | 0.9882   | <u>0.9849</u>  |
| <u>91</u>                | <u>0.9849</u>   | 0.9882   | 0.9866   |
| <u>92</u>                | <u>0.9833</u>   | 0.9849   | 0.9866   |
| <u>93</u>                | <u>0.9833</u>   | 0.9849   | 0.9882   |
| <u>94</u>                | <u>0.9816</u>   | <u>0.9849</u>  | <u>0.9849</u>  |
| <u>95</u>                | <u>0.9816</u>   | <u>0.9849</u>  | <u>0.9849</u>  |
| <u>96</u>                | <u>0.9816</u>   | 0.9849   | <u>0.9849</u>  |
| <u>97</u>                | <u>0.9816</u>   | 0.9833   | <u>0.9849</u>  |
| <u>98</u>                | <u>0.9816</u>   | 0.9833   | 0.9849   |
| <u>99</u>                | <u>0.9799</u>   | 0.9816   | 0.9833   |
| 100                      | <u>0.9833</u>   | 0.9816   | 0.9833   |
| 101                      | 0.9833  | 0.9816   | 0.9816   |
| <u>102</u>               | <u>0.9866</u>   | 0.9816   | 0.9816   |
| <u>103</u>               | <u>0.9866</u>   | 0.9816   | 0.9816   |
| <u>104</u>               | <u>0.9866</u>   | 0.9833   | 0.9816   |
| <u>105</u>               | <u>0.9866</u>   | 0.9833   | 0.9816   |
| <u>106</u>               | <u>0.9866</u>   | 0.9849   | 0.9799   |
| <u>107</u>               | <u>0.9866</u>   | 0.9866   | 0.9799   |
| 108                      | 0.9882  | 0.9866   | 0.9799   |
| <u>109</u>               | <u>0.9882</u>   | <u>0.9866</u>  | <u>0.9833</u>  |
| <u>110</u>               | <u>0.9849</u>   | <u>0.9866</u>  | <u>0.9833</u>  |
| <u>111</u>               | <u>0.9849</u>   | <u>0.9882</u>  | <u>0.9849</u>  |
| 112                      | <u>0.9833</u>   | 0.9866   | <u>0.9866</u>  |
| <u>113</u>               | <u>0.9833</u>   | 0.9882   | 0.9866   |
| <u>114</u>               | <u>0.9833</u>   | 0.9882   | <u>0.9849</u>  |
| <u>115</u>               | <u>0.9799</u>   | 0.9849   | <u>0.9849</u>  |
| <u>116</u>               | <u>0.9766</u>   | <u>0.9849</u>  | <u>0.9866</u>  |



| Candidate<br>height (cm) | Proportion for Candidates in Diagnosis Groups A and <u>C</u> | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--------------------------|--|--|--|
| <u>117</u>               | <u>0.9701</u>  | <u>0.9833</u>  | <u>0.9833</u>  |
| 118                      | <u>0.9619</u>  | 0.9833   | 0.9849   |
| <u>119</u>               | <u>0.9603</u>  | 0.9833   | 0.9833   |
| <u>120</u>               | <u>0.9442</u>  | <u>0.9799</u>  | <u>0.9816</u>  |
| <u>121</u>               | <u>0.9394</u>  | <u>0.9766</u>  | <u>0.9816</u>  |
| <u>122</u>               | <u>0.9268</u>  | <u>0.9652</u>  | <u>0.9799</u>  |
| <u>123</u>               | <u>0.9206</u>  | 0.9603   | <u>0.9766</u>  |
| <u>124</u>               | <u>0.9175</u>  | 0.9603   | 0.9701   |
| <u>125</u>               | <u>0.8825</u>  | 0.9442   | <u>0.9619</u>  |
| <u>126</u>               | <u>0.8810</u>  | 0.9394   | 0.9603   |
| <u>127</u>               | <u>0.8247</u>  | 0.9206   | 0.9442   |
| <u>128</u>               | <u>0.7933</u>  | <u>0.9206</u>  | 0.9394   |
| <u>129</u>               | <u>0.7879</u>  | 0.9175   | 0.9268   |
| <u>130</u>               | <u>0.7130</u>  | <u>0.8825</u>  | <u>0.9175</u>  |
| <u>131</u>               | <u>0.7118</u>  | 0.8810   | <u>0.9144</u>  |
| 132                      | <u>0.6235</u>  | 0.7986   | 0.8825   |
| <u>133</u>               | <u>0.5776</u>  | 0.7933   | 0.8810   |
| <u>134</u>               | <u>0.5698</u>  | 0.7892   | <u>0.8247</u>  |
| <u>135</u>               | <u>0.4756</u>  | 0.7130   | 0.7919   |
| <u>136</u>               | <u>0.4359</u>  | 0.7105   | <u>0.7866</u>  |
| <u>137</u>               | <u>0.4220</u>  | 0.6235   | 0.7118   |
| <u>138</u>               | <u>0.3223</u>  | <u>0.5776</u>  | <u>0.7105</u>  |
| 139                      | <u>0.3129</u>  | <u>0.5708</u>  | 0.6235   |
| 140                      | <u>0.2375</u>  | 0.4435   | <u>0.5776</u>  |
| 141                      | <u>0.2106</u>  | <u>0.4345</u>  | <u>0.5698</u>  |
| 142                      | <u>0.2047</u>  | 0.4220   | 0.4748   |
| <u>143</u>               | <u>0.1359</u>  | 0.3223   | <u>0.4352</u>  |
| 144                      | <u>0.1316</u>  | 0.3129   | 0.4220   |
| <u>145</u>               | 0.0998   | 0.2173   | 0.3223   |
| <u>146</u>               | <u>0.0897</u>  | 0.2091   | 0.3129   |
| <u>147</u>               | <u>0.0865</u>  | 0.2051   | 0.2375   |
| <u>148</u>               | <u>0.0590</u>  | <u>0.1359</u>  | <u>0.2106</u>  |
| <u>149</u>               | 0.0576   | 0.1316   | 0.2047   |



| Candidate<br>height (cm) | Proportion for Candidates in Diagnosis Groups A and <u>C</u> | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--------------------------|--|--|--|
| <u>150</u>               | <u>0.0447</u>  | <u>0.0910</u>  | <u>0.1357</u>  |
| <u>151</u>               | 0.0388   | 0.0897   | 0.1314   |
| <u>152</u>               | <u>0.0376</u>  | 0.0869   | 0.0998   |
| <u>153</u>               | <u>0.0226</u>  | <u>0.0590</u>  | 0.0893   |
| <u>154</u>               | <u>0.0222</u>  | <u>0.0576</u>  | <u>0.0862</u>  |
| <u>155</u>               | <u>0.0161</u>  | 0.0401   | <u>0.0587</u>  |
| <u>156</u>               | 0.0142   | 0.0390   | 0.0574   |
| <u>157</u>               | 0.0134   | 0.0379   | 0.0447   |
| <u>158</u>               | 0.0072   | 0.0227   | 0.0387   |
| <u>159</u>               | 0.0070   | 0.0221   | 0.0373   |
| <u>160</u>               | <u>0.0055</u>  | 0.0143   | 0.0221   |
| <u>161</u>               | <u>0.0051</u>  | 0.0142   | <u>0.0217</u>  |
| <u>162</u>               | <u>0.0049</u>  | 0.0137   | 0.0157   |
| <u>163</u>               | <u>0.0045</u>  | 0.0072   | <u>0.0137</u>  |
| <u>164</u>               | <u>0.0046</u>  | 0.0070   | 0.0129   |
| <u>165</u>               | <u>0.0046</u>  | 0.0061   | 0.0067   |
| <u>166</u>               | 0.0052   | 0.0051   | 0.0066   |
| <u>167</u>               | 0.0052   | 0.0059   | 0.0053   |
| <u>168</u>               | 0.0080   | 0.0046   | 0.0045   |
| <u>169</u>               | 0.0082   | 0.0047   | 0.0043   |
| <u>170</u>               | 0.0084   | 0.0061   | 0.0031   |
| <u>171</u>               | 0.0133   | 0.0052   | 0.0031   |
| <u>172</u>               | <u>0.0137</u>  | 0.0073   | 0.0039   |
| <u>173</u>               | <u>0.0163</u>  | 0.0082   | <u>0.0036</u>  |
| <u>174</u>               | <u>0.0215</u>  | 0.0084   | 0.0037   |
| <u>175</u>               | <u>0.0224</u>  | <u>0.0136</u>  | <u>0.0049</u>  |
| <u>176</u>               | 0.0362   | <u>0.0136</u>  | 0.0048   |
| <u>177</u>               | 0.0378   | 0.0144   | 0.0068   |
| <u>178</u>               | 0.0438   | 0.0215   | 0.0079   |
| <u>179</u>               | 0.0617   | 0.0224   | 0.0081   |
| <u>180</u>               | 0.0640   | 0.0361   | 0.0132   |
| <u>181</u>               | 0.0939   | <u>0.0375</u>  | <u>0.0135</u>  |
| <u>182</u>               | 0.0955   | 0.0388   | 0.0142   |



| Candidate<br>height (cm) | Proportion for Candidates in Diagnosis Groups A and <u>C</u> | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--------------------------|--|--|--|
| <u>183</u>               | <u>0.1090</u>  | <u>0.0617</u>  | <u>0.0215</u>  |
| 184                      | 0.1427   | 0.0639   | 0.0224   |
| <u>185</u>               | 0.1458   | 0.0939   | <u>0.0359</u>  |
| <u>186</u>               | <u>0.2008</u>  | <u>0.0953</u>  | <u>0.0373</u>  |
| <u>187</u>               | <u>0.2084</u>  | <u>0.0987</u>  | <u>0.0386</u>  |
| 188                      | 0.2128   | <u>0.1427</u>  | 0.0617   |
| 189                      | 0.3189   | <u>0.1458</u>  | 0.0639   |
| 190                      | 0.3256   | <u>0.1823</u>  | 0.0939   |
| <u>191</u>               | <u>0.4397</u>  | 0.2062   | 0.0953   |
| <u>192</u>               | <u>0.4473</u>  | 0.2124   | 0.0987   |
| <u>193</u>               | <u>0.4589</u>  | <u>0.3189</u>  | <u>0.1427</u>  |
| <u>194</u>               | <u>0.6440</u>  | <u>0.3250</u>  | <u>0.1458</u>  |
| <u>195</u>               | <u>0.6539</u>  | <u>0.4036</u>  | <u>0.1823</u>  |
| <u>196</u>               | <u>0.7591</u>  | <u>0.4435</u>  | <u>0.2062</u>  |
| <u>197</u>               | <u>0.7668</u>  | <u>0.4589</u>  | 0.2124   |
| 198                      | <u>0.7773</u>  | <u>0.6440</u>  | <u>0.3189</u>  |
| 199                      | <u>0.8795</u>  | <u>0.6539</u>  | <u>0.3250</u>  |
| 200                      | <u>0.8840</u>  | <u>0.7154</u>  | <u>0.4036</u>  |
| 201                      | <u>0.9021</u>  | <u>0.7643</u>  | <u>0.4435</u>  |
| 202                      | 0.9458   | <u>0.7773</u>  | <u>0.4589</u>  |
| 203                      | <u>0.9458</u>  | <u>0.8795</u>  | 0.6440   |
| 204                      | <u>0.9684</u>  | <u>0.8825</u>  | <u>0.6539</u>  |
| <u>205</u>               | <u>0.9750</u>  | <u>0.8900</u>  | <u>0.7154</u>  |
| 206                      | 0.9783   | <u>0.9458</u>  | <u>0.7643</u>  |
| 207                      | 0.9882   | <u>0.9458</u>  | <u>0.7773</u>  |
| 208                      | 0.9882   | <u>0.9684</u>  | <u>0.8795</u>  |
| 209                      | 0.9949   | 0.9733   | 0.8825   |
| 210                      | 0.9949   | <u>0.9750</u>  | 0.8900   |
| 211                      | 0.9949   | 0.9882   | 0.9458   |
| 212                      | 0.9949   | 0.9882   | 0.9458   |
| 213                      | 0.9966   | <u>0.9949</u>  | 0.9684   |
| 214                      | 1.0000   | 0.9949   | 0.9733   |
| <u>215</u>               | 1.0000   | 0.9949   | 0.9750   |



| <u>Candidate</u><br><u>height (cm)</u> | Proportion for Candidates in Diagnosis Groups A and <u>C</u> | Proportion for<br>Candidates in Diagnosis<br>Group B | Proportion for<br>Candidates in Diagnosis<br>Group D |
|--|--|--|--|
| <u>216</u>                             | <u>1.0000</u>  | <u>0.9949</u>  | <u>0.9882</u>  |
| <u>217</u>                             | <u>1.0000</u>  | <u>0.9966</u>  | <u>0.9882</u>  |
| <u>218</u>                             | <u>1.0000</u>  | <u>1.0000</u>  | <u>0.9949</u>  |
| <u>219</u>                             | <u>1.0000</u>  | <u>1.0000</u>  | <u>0.9949</u>  |
| <u>220</u>                             | <u>1.0000</u>  | <u>1.0000</u>  | <u>0.9949</u>  |
| <u>221</u>                             | <u>1.0000</u>  | <u>1.0000</u>  | <u>0.9949</u>  |
| <u>222</u>                             | <u>1.0000</u>  | <u>1.0000</u>  | <u>0.9966</u>  |
| 223 or more                            | <u>1.0000</u>  | 1.0000   | <u>1.0000</u>  |

| 1154 | Appendix A: L | ung Review Boar | d Operational | Guidelines |
|------|---------------|-----------------|---------------|------------|
|      |               |                 | • p •         |            |

1155

1156

# **Lung Review Board Operational Guidelines**

### 1157 Overview

- The purpose of the Lung Review Board (Review Board) is to provide fair, equitable, and prompt peer
   review of exception requests. The Review Board will review these exception requests and determine if
- the request is comparable to other candidates registered at the same status.

11611162

## **Representation**

<u>Policy 10.2 Lung Composite Score Exceptions</u> sets the structure and composition of the Lung Review <u>Board.</u>

1164 1165 1166

1167

1168

1169

1170

1171

11721173

1174

11751176

1177

11781179

1180 1181

1182

1183

1184

1185

11861187

1188 1189

1190

1191

1163

- The membership of the Lung Review Board will be comprised of 9 individual lung transplant surgeons or lung transplant physicians. Each active lung transplant program shall have the opportunity to rotate onto the review board. Qualifications to serve on the Lung Review Board include:
  - The review board representative must be employed at an active lung transplant program.
    - o If a transplant hospital inactivates or withdraws its lung program, the review board representative from that hospital may not participate in the Review Board. The term of the transplant hospital's representative on the Review Board ends upon program's inactivation or withdrawal from the OPTN. Another eligible transplant program will be contacted at random and requested to put forth a representative and an alternate to replace the departed member. Should a transplant program reactivate, it may again have the opportunity to be represented on the LRB during future rotations.
    - It is the responsibility of each transplant program to provide the OPTN Contractor with the contact information for the both the primary review board representative and the alternate from their program. Should a representative leave his transplant program, then the program's alternate representative will become the review board member and another alternate will be appointed. The departing member will be removed from the review board.
  - Review board members serve a term of 2 years. Service terms will be staggered among the LRB members to ensure that at no time more than 5 terms will end. This requirement is to preserve the continuity of the LRB and the efficiency of its operation. If additional LRB representatives are to be appointed to the LRB due to a change in the operational guidelines, the Chair of the OPTN Lung Transplantation Committee (Committee) will select the additional members and establish the terms of their initial appointment.
  - <u>Six review board members represent active adult lung transplant programs and 3 members represent active pediatric lung transplant programs.</u>
  - The Chair of the Committee will appoint a primary review board member to serve as the Review Board Chair for a 2-year term.

11921193

## 1194 Representatives Responsibilities

1195 Review board representatives must:

- A. <u>Vote within on all exception requests, exception extension requests, and appeals according to</u> the timelines set by policy.
- B. <u>Provide an explanation for the disapproval to the candidate's lung program when voting to not approve.</u>
- C. Participate on conference calls as they are scheduled.
- D. Notify the OPTN of any planned absences. The majority required to close a request will be affected by notification of planned absences. Requests will not be assigned to representatives who are known to be unavailable to review requests.
- E. <u>Each review board member is required to appoint an alternate representative from his</u> transplant program.

1207 Voting Procedure

A Review Board representative's vote will not be valid and will not count towards the majority in any case in which the representative has a conflict of interest. Review Board members will not be assigned cases from their own transplant hospital.

The OPTN Contractor will send the application or appeal to LRB members. If the Review Board member has not voted within three days of when the OPTN Contractor sends the application or appeal to the LRB, then the OPTN Contractor will send the case to the alternate. Thereafter, both the LRB member and alternate may vote on the application within five days of when the OPTN Contractor originally sent the application to the LRB. If the LRB member and the alternate both submit votes for the same application, then the OPTN Contractor will count the vote from whomever voted first.

The review board will review all exception requests prospectively. The candidate will not receive the exception score unless or until it is approved.

Review board representatives will have five days to vote and exception requests will be decided as follows:

| If the vote is               | The request is |
|------------------------------|----------------|
| Majority vote to approve     | Approved       |
| Majority vote to not approve | <u>Denied</u>  |
| No majority met              | Approved       |

A majority vote requires more than half of the representatives voting on the application.

Voting will close at the earliest of when:

- A majority of all eligible voters have voted to approve or not approve an exception request
- The timeline elapses for the review board members to vote on the exception request.

| Appeal Process  |
|---|
| A candidate's lung program may appeal the review board's decision to deny an exception request within   |
| seven days of receiving the denial notification. All representative comments of denied requests are     |
| provided to the lung program. The program must submit additional written information justifying or      |
| amending the requested exception and may include responses to the comments of dissenting review         |
| board representatives. This additional information will be provided to the review board representatives |
| for further consideration.  |
|   |
| If the first appeal request is denied, the lung program may request a conference call with the Review   |
| Board for an appeal. A representative at the petitioning program may serve as the candidate's advocate  |
| on the call. Five members of the Review Board must participate in the call. If after two attempts, five |
| review board members do not call in, the appeal will be marked as approved.                             |
|   |
| Following a denial on a conference call, the candidate's lung program can appeal to the Committee. The  |
| lung program must appeal within 14 days of notification. The program can provide additional written     |
| information justifying the requested exception status to be sent to the Committee. The Committee will   |
| approve or not approve each appeal on the next scheduled Committee call following the request to the    |
| Committee.  |
|   |



## **Appendix B: Glossary of Terms**

The following terms are used throughout the proposal.

#### **Attribute**

Attributes are criteria we use to classify then sort and prioritize candidates. For example, in lung allocation, our criteria include medical urgency, travel mode, ischemic time, blood type compatibility, and others.

#### Classification-based framework

A classification-based framework groups similar candidates into classifications or groupings. We then sort candidates within those classifications. A candidate will only appear in the classification that is most beneficial to them. This is the framework currently used to allocate organs.

#### Cliff

Cliffs are an illustrative term to describe hard boundaries in the attributes used to prioritize candidates. For example, the zones used in concentric circles have hard boundaries at specific distances. Continuous distribution and the move to a points-based framework aim to smooth these hard boundaries.

#### **Composite Allocation Score**

The scoring system used to prioritize candidates on the match run. It ranges from 0-100 and is an aggregate of separate goal level scores.

#### **Continuous Distribution**

Continuous distribution was the phrase used in the 2018 Snyder article and by the Ad Hoc Geography Committee to describe a new framework for organ distribution. It utilizes points to prioritize candidates for organ transplant.

#### **Distance**

The distance between the donor hospital and transplant hospital is either the straight line or travel distance. Straight line distance is the current method for calculating distance and represents the shortest two points. Travel distance is the most likely distance that the organ would travel between two points. For example, a straight line distance would be the shortest distance between hospitals on either side of a body of water; whereas, the travel distance would be the distance that somebody might drive on the roads and bridges around the body of water.

#### **Framework**

A collection of policies and procedures used to distribute organs. Examples include concentric circles and continuous distribution.

#### **Points**

Points are awarded for each attribute. The total points within a single goal are equal to the score for that goal. The total points for all attributes are equal to the composite allocation score.



#### Points-based framework

A points-based framework gives each candidate a score or points. Organs are then offered in descending order based upon the candidate's score. This concept paper proposes a points-based framework for organ allocation.

#### **Rating Scale**

A rating scale describes how much preference is provided to candidates within each attribute. For example, if all else is equal, should a candidate with an LAS 80 receive twice as much priority as a candidate with an LAS 40? Applying the rating scale to each candidate's information and combining it with the weight of the attribute results in an overall composite score for prioritizing candidates.

### **Revealed Preference Analysis (RPA)**

A revealed preference analysis looks at actual decisions to determine the implicit preferences of the decision maker. This is compared with a stated preference analysis (for example, AHP or DCE) that asks the decision maker to state their preferences in an experiment.

#### Score

A candidate is assigned a score for each goal. The score for a goal is equal to the total points for the attributes within that goal. The total of the scores for all goals is equal to the candidate's composite allocation score.

#### **Stated Preference**

A stated preference analysis asks participants to state their preferences in a pairwise comparison. AHP and DCE are examples of stated preference analysis.

### Weight

Weights are the relative importance or priority of each attribute toward our overall goal of organ allocation. For example, should waitlist mortality be more or less important than post-transplant outcomes? Combined with the ratings scale and each candidate's information, this results in an overall composite score for prioritizing candidates.