

Briefing to the OPTN Board of Directors on

Update Data Collection for Lung Mortality Models

OPTN Lung Transplantation Committee

*Prepared by: Kaitlin Swanner
UNOS Policy and Community Relations Department*

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Update Data Collection for Lung Mortality Models

<i>Affected Policies:</i>	<i>10.1.F Lung Disease Diagnosis Groups 21.2.A Values Used in the Calculation of Lung Waiting List Survival 21.2.B.1 Coefficients Used in Calculating Lung Post-Transplant Outcomes</i>
<i>Data Collection Affected:</i>	<i>Lung OPTN Waiting List Lung Data System for Organ Procurement and Transplantation Network</i>
<i>Sponsoring Committee:</i>	<i>Lung Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022-September 28, 2022</i>
<i>Board of Directors Meeting:</i>	<i>December 5, 2022</i>

Executive Summary

In both the current and future lung allocation systems, estimates of waiting list survival and post-transplant survival are calculated based on clinical information reported for lung candidates while they are on the waiting list. The coefficients used in those calculations are based on mortality models that estimate how much each clinical criterion impacts a candidate's mortality.

The OPTN Lung Transplantation Committee proposes updates to the clinical information collected on lung candidates, including removing data collection not used to calculate the allocation score; revising data collection to improve data quality; and adding data collection on clinical criteria to evaluate if such criteria should be incorporated into the mortality models in the future.



Purpose

The purpose of this proposal is to update data collection in OPTN Waiting List and the Data System for Organ Procurement and Transplantation Network on disease severity of lung candidates by removing, revising, and adding data collection. This proposal would not change the variables, coefficients, rating scales, or weights used to calculate the lung composite allocation score. However, this proposal would assign values for parts of the score for candidates on extracorporeal membrane oxygenation (ECMO) or high flow nasal cannula so that these candidates' scores are not negatively impacted by the proposed data collection changes.

Background

The current lung allocation score is based on estimates of a candidate's waiting list survival and post-transplant survival.¹ In December 2021, the OPTN Board of Directors approved a new lung composite allocation score² that incorporates:

- Candidate's expected 1-year waiting list survival
- Candidate's expected 5-year post-transplant outcomes
- Candidate's blood type
- Candidate's level of sensitization
- Candidate's height
- Whether a candidate is under 18 years old at time of registration
- Whether the candidate is a prior living organ donor
- Travel efficiency
- Proximity efficiency

In both the current and future lung allocation systems, estimates of waiting list survival and post-transplant survival are calculated based on clinical information reported for lung candidates while they are on the waiting list. The coefficients used in those calculations are based on mortality models that estimate how much each clinical criterion impacts a candidate's mortality.

As the OPTN Lung Transplantation Committee (Committee) was developing the new lung composite allocation score, the Committee proposed several improvements to the waiting list and post-transplant survival scores. These improvements were approved by the OPTN Board of Directors and implemented. First, the cohort of candidates used for the mortality models was updated to ensure that the estimates of waiting list survival and post-transplant outcomes were based on more recent data.³ These changes were implemented on September 30, 2021,⁴ along with some additional refinements to lung data fields.^{5,6} Second, the proposal to *Establish Continuous Distribution of Lungs*⁷ changed how the waiting

¹ "A Guide to Calculating the Lung Allocation Score," OPTN, accessed July 7, 2022, <https://optn.transplant.hrsa.gov/media/cn0iv5zv/a-guide-to-calculating-the-lung-allocation-score.pdf>.

² "A Guide to Calculating the Lung Composite Allocation Score," OPTN, accessed October 7, 2022, https://optn.transplant.hrsa.gov/media/jhcppfnd/guide_to_calculating_lung_composite_allocation_score.pdf.

³ "Updated Cohort for Calculation of the Lung Allocation Score," OPTN, accessed June 7, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/updated-cohort-for-calculation-of-the-lung-allocation-score-las/>.

⁴ Notice of Implemented Actions, OPTN, accessed June 7, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/>.

⁵ "Refine Lung Data Fields," OPTN, accessed June 19, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/refine-lung-data-fields/>

⁶ Executive Committee Meeting Summary for July 30, 2021, OPTN, accessed June 19, 2022, https://optn.transplant.hrsa.gov/media/2s4na4hw/20210730_executive_committee_summary.pdf.

⁷ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed June 29, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

list survival and post-transplant outcomes scores factor into allocation. For the waiting list survival score, there was no change to the mortality model inputs used to determine this score, but there were updates to how waiting list survival estimates translate into points for each candidate. Points are assigned on a curved scale, so that patients who are estimated to live few days without a transplant receive many more points than patients who are estimated to live closer to a year without transplant. For the post-transplant outcomes score, the mortality model was updated to estimate five years of post-transplant survival rather than one-year post-transplant survival, which included some changes to the variables and coefficients used in the calculation.

To build upon these improvements, the Committee proposes additional updates to data collection on lung candidates, including removing data collection not used to calculate the allocation score and revising data collection to improve data quality. Based on clinical literature, historic review board exception requests, and community feedback, the Committee also identified other clinical criteria not currently captured in the mortality models that may impact a lung candidate's expected waiting list survival or post-transplant outcomes. The Committee proposes adding data collection on these clinical criteria. Once sufficient data has been collected, the Committee will request that the Scientific Registry of Transplant Recipients (SRTR) evaluate the mortality models with the updated data. This analysis will determine if using the new data in the mortality models will improve their ability to predict a candidate's waiting list survival and post-transplant outcomes. The current waitlist mortality model is fit to a dataset with approximately four years of follow-up on lung candidates, and the SRTR estimates that at least two years of follow-up would be needed on the proposed data additions to consider refitting the model. Any updates to the mortality models and, consequently, the calculation of the lung CAS based on the proposed data collection would be released for public comment as a future proposal.

Proposal for Board Consideration

The Committee proposes several changes to data collection for lung candidates in OPTN Waiting List and Data System for OPTN, including removing data collection on five clinical criteria; revising data collection for seven other clinical criteria; and adding data collection on nine clinical criteria. The Committee also proposes adding serial data collection for three clinical criteria, two of which are currently collected by the OPTN and one which is not. Serial data collection allows transplant programs to enter data for multiple dates.

Some of the proposed changes also require updates to policy. The proposed data collection and policy changes are summarized below, and additional details on the data collection, including the proposed data definitions, are included at the end of this proposal.

Data Removals

The Committee proposes removing data collection on five clinical criteria, as summarized in **Table 1**, because they are not used to estimate a candidate's waitlist survival or post-transplant outcomes. For some of these criteria, the values can be calculated from other data already collected.

Table 1: Proposed Removals

Clinical Criteria	Rationale
Percent Predicted Forced Vital Capacity (FVC)	This variable is not used to calculate a candidate’s waitlist survival or post-transplant outcomes, and can be calculated using other data that is entered such as height, weight, and birth sex. ^{8,9,10} While used in earlier iterations of LAS, this variable was removed from the score for diagnosis groups A, B, and C following a 2012 proposal, ¹¹ and removed from the score for diagnosis group D in 2021. ¹² Actual forced vital capacity will still be collected in OPTN Waiting List.
Post Bronchodilator Actual FEV ₁	This variable has been collected as part of the Pulmonary Function Test data in OPTN Waiting List but is not used to calculate a candidate’s waitlist survival or post-transplant outcomes. ¹³
Pre Bronchodilator Percent Predicted FEV ₁	This variable has been collected as part of the Pulmonary Function Test data in OPTN Waiting List but is not used to calculate a candidate’s waitlist survival or post-transplant outcomes, and can be calculated from other data submitted. ¹⁴
Post Bronchodilator Percent Predicted FEV ₁	This variable has been collected as part of the Pulmonary Function Test data in OPTN Waiting List but is not used to calculate a candidate’s waitlist survival or post-transplant outcomes. ¹⁵
Requires Supplemental O ₂ : How was the value obtained	<p>This field indicates whether entered values were calculated from a formula or read from an oxygen delivery device. This field is not used to calculate a candidate’s waitlist survival or post-transplant outcomes and would no longer be needed based on the proposed updates to data collection on supplemental O₂.</p> <p>If values used to calculate the allocation score are entered in units of fraction of inspired oxygen (%), the OPTN Computer System will convert these values to L/min.¹⁶</p>

⁸ “Spirometry Reference Value Calculator,” National Institute for Occupational Safety and Health, accessed June 23, 2022, <https://www.cdc.gov/niosh/topics/spirometry/refcalculator.html>.

⁹ John L. Hankinson, John R. Odencrantz, and Kathleen B. Fedan, “Spirometric Reference Values from a Sample of the General U.S. Population,” *American Journal of Respiratory and Critical Care Medicine* 159 no. 1 (1999):179-187, DOI: 10.1164/ajrccm.159.1.9712108.

¹⁰ Lung Transplantation Committee Meeting Summary, March 17, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/mt5hxakr/20220317_lung-committee-meeting-summary_draft.pdf

¹¹ “Proposal to Revise the Lung Allocation Score System,” OPTN, Briefing Paper, 2012.

¹² “Updated Cohort for Calculation of the Lung Allocation Score,” OPTN, Briefing Paper, accessed October 21, 2022, https://optn.transplant.hrsa.gov/media/kvsloxtl/bp_202012_updated-cohort-for-calculation-of-the-lung-allocation-score.pdf.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ The conversion is 3% per liter, per minute after subtracting 21% (to account for room air). For example, 30% O₂ converts to 3 L/min: (30% - 21%) / 3% per L/min = 3 L/min.

Data Revisions

The Committee proposes revising data collection on seven clinical criteria that are currently collected by the OPTN, as summarized in **Table 2**. These revisions are expected to improve data quality to more accurately estimate a candidate’s waitlist survival and post-transplant outcomes.

Table 2: Proposed Revisions

Clinical Criteria	Rationale
Lung Diagnosis Code – addition of <i>Combined Pulmonary Fibrosis and Emphysema (CPFE)</i>	Transplant programs have submitted exception requests for candidates with CPFE. ¹⁷ Candidates reported to have CPFE were registered under the diagnosis code of <i>Idiopathic Pulmonary Fibrosis (IPF)</i> , which may not accurately reflect the severity of disease, according to clinical literature which suggests that these candidates have worse outcomes. ^{18,19,20,21} The Committee proposes adding the CPFE diagnosis code in order to evaluate if these candidates do have worse outcomes and should be assigned additional points in the CAS. ^{22,23} The code would be added under diagnosis group D, since IPF falls into this group and that is how these candidates are registered currently.
Diabetes	The revisions would remove references to insulin “dependency” and instead request that programs indicate if the candidates are <i>treated</i> with insulin, since insulin use (rather than dependency) is associated with a higher risk of mortality. ^{24,25} These changes would also improve data quality by making the data collection more objective since transplant programs would report whether the candidate is treated with insulin but would not have to determine whether they would characterize the candidate as insulin dependent.

¹⁷ Per clinical narratives submitted to the OPTN for patients with exception requests between January 1, 2019, and December 31, 2020.
¹⁸ Matthew D. Jankowich and Sharon I.S. Rounds, “Combined pulmonary fibrosis and emphysema syndrome: a review,” *Chest* 141 no. 1 (2012): 222-231, DOI: 10.1378/chest.11-1062.
¹⁹ Lijuan Zhang, Chunling Zhang, and Fushi Dong, et al., “Combined pulmonary fibrosis and emphysema: a retrospective analysis of clinical characteristics, treatment and prognosis,” *BMC Pulmonary Medicine* 16 no. 1 (2016): 137, DOI: 10.1186/s12890-016-0300-7.
²⁰ An Zhao, Eyjolfur Gudmundsson, and Nesrin Mogulkoc, et al., “Mortality in CPFE patients is determined by the sum of pulmonary fibrosis and emphysema,” *ERJ Open Research* 8 no. 2 (2021), DOI: 10.1183/23120541.00316-2021.
²¹ Tomoo Kishaba, Yousuke Shimaoka, and Hajime Fukuyama, et al., “A cohort study of mortality predictors and characteristics of patients with combined pulmonary fibrosis and emphysema,” *BMJ Open* 2(2012): e000988, DOI: 10.1136/bmjopen-2012-000988.
²² Ibid.
²³ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, April 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/4620/20210422_lung-umm-subcommittee-meeting-summary.pdf
²⁴ J.M. Gamble, S.H. Simpson, and D.T. Eurich, et al., “Insulin use and increased risk of mortality in type 2 diabetes: a cohort study,” *Diabetes, Obesity, & Metabolism* 12 no. 1 (2010):47-53, doi: 10.1111/j.1463-1326.2009.01125.x.
²⁵ Ibid.

Clinical Criteria	Rationale
Assisted Ventilation	<p>The proposed revisions include adding options for “intermittent mechanical – hospitalized” and “intermittent mechanical – not hospitalized.” The Committee proposes differentiating between these situations since it is likely that patients who are hospitalized are sicker than those who are not, and if someone had to be hospitalized while on intermittent mechanical ventilation, it would likely be due to their oxygen requirements.²⁶ The Committee discussed including an option for average volume-assured pressure support (AVAPS) but determined that use of AVAPS should be reported as “intermittent mechanical.”</p> <p>If extracorporeal membrane oxygenation (ECMO) is selected, the Committee proposes allowing the transplant program to select if the candidate is on venoarterial (VA) or venovenous (VV) ECMO, and whether or not the candidate is also mechanically ventilated.</p>
Requires Supplemental O ₂	<p>Current data collection on supplemental O₂ is limited and does not reflect the diversity of devices used to supply oxygen. The revisions would allow transplant programs to enter more detailed and accurate data related to oxygen delivery devices, as detailed below this table and in Table 3. The revisions would also allow the transplant programs to report the amount of supplemental oxygen delivered with exercise, with sleep, and at rest, whereas currently transplant programs can only enter the amount of supplemental oxygen needed at one of these activity levels. These changes are expected to improve data quality through consistency with how data is entered for various clinical circumstances.^{27,28,29}</p>

²⁶ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, February 3, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/3c4otx32/20220203_lung-umm-subcommittee-meeting-summary.pdf

²⁷ Ibid.

²⁸ Lung Transplantation Committee Meeting Summary, March 17, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/mt5hxakr/20220317_lung-committee-meeting-summary_draft.pdf

²⁹ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, January 6, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/aj4dy11o/20220106_lung-umm-subcommittee-meeting-summary.pdf

Clinical Criteria	Rationale
Six Minute Walk Distance	<p>The proposed revisions to this field include moving its placement under <i>Requires Supplemental O₂</i> since these data are often collected and entered at the same time by transplant coordinators.</p> <p>Additionally, the data definition would be modified to specify that this should be the <i>total exertional distance performed on a flat surface</i> (the current definition refers simply to the “distance the candidate is able to walk in six minutes in feet”). This change is intended to improve consistency across transplant programs in how they enter data on the six-minute walk, since the Committee noted that there is not a reliable standard in the field for how to perform the six-minute walk and practice varies between programs.^{30,31}</p>
Prior Lung Surgery	<p>Prior lung surgery is currently collected on the Transplant Recipient Registration (TRR). The Committee proposes removing this data collection from the TRR and adding it to the Transplant Candidate Registration (TCR) to reflect the patient’s history of prior lung surgery at the time of listing. The Committee proposes updating the selection options to better capture procedures that can lead to scarring, which may make lung transplant more difficult and potentially impact post-transplant outcomes.^{32,33,34}</p>
Prior Cardiac Surgery	<p>Prior cardiac surgery is currently collected on the TCR and the TRR. The Committee proposes removing this data collection from the TRR and updating the selection options on the TCR to better capture procedures that can lead to scarring, which may make lung transplant more difficult and potentially impact post-transplant outcomes.^{35,36,37}</p>

³⁰ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, May 27, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/4706/20210527_lung-umm-subcommittee-meeting-summary.pdf

³¹ Lung Transplantation Committee Meeting Summary, May 13, 2022, OPTN, accessed June 10, 2022, https://optn.transplant.hrsa.gov/media/uo1jchw4/20220513_lung-committee-meeting-summary.pdf.

³² N. Shigemura, J. Bhama, and C.J. Gries, et al., “Lung Transplantation in Patients with Prior Cardiothoracic Surgical Procedures,” *American Journal of Transplantation* 12 (2012):1249-1255, <https://doi.org/10.1111/j.1600-6143.2011.03946.x>.

³³ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, February 3, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/3c4otx32/20220203_lung-umm-subcommittee-meeting-summary.pdf

³⁴ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, December 2, 2021, OPTN, accessed March 23, 2022, https://optn.transplant.hrsa.gov/media/uwalxqmp/20211202_lung-umm-subcommittee-meeting-summary_draft.pdf

³⁵ N. Shigemura, J. Bhama, and C.J. Gries, et al., “Lung Transplantation in Patients with Prior Cardiothoracic Surgical Procedures,” *American Journal of Transplantation* 12 (2012):1249-1255, <https://doi.org/10.1111/j.1600-6143.2011.03946.x>.

³⁶ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, February 3, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/3c4otx32/20220203_lung-umm-subcommittee-meeting-summary.pdf

³⁷ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, December 2, 2021, OPTN, accessed March 23, 2022, https://optn.transplant.hrsa.gov/media/uwalxqmp/20211202_lung-umm-subcommittee-meeting-summary_draft.pdf

Requires Supplemental O₂

Current data collection on supplemental oxygen only allows transplant programs to enter the amount of supplemental oxygen needed at one activity level: either at rest, at night, or with exercise only. It does not allow transplant programs to indicate if candidates have different supplemental oxygen needs at rest, at night, and with exercise. The OPTN has also received member questions asking when to use “at rest” versus “at night,” which is why the Committee proposes changing the option for “at night” to “with sleep.” Only values entered for supplemental oxygen requirements “at rest” factor into the calculation of the lung CAS. Members may enter the amount of oxygen in either L/min to indicate the flow rate or in % to indicate the fraction of inspired oxygen (FiO₂), which is the concentration of oxygen in the gas mixture. However, the allocation score calculation only uses values of L/min, so the computer system converts values entered in percent to L/min.³⁸

The Committee proposes updating this data collection to allow transplant programs to indicate the type of device used to supply oxygen to collect more precise data on a candidate’s clinical condition. The permitted units of measurement for supplemental oxygen would vary based on the device used, as outlined in **Table 3**.

Table 3. Permitted Values by Device Type for Supplemental Oxygen

Device	Permitted Values	Computer System Actions
High flow nasal cannula	Both L/min and %	Convert % to L/min and use higher of the two values
Face mask	% only	Convert % to L/min
Nasal cannula	L/min only	--
Reservoir cannula	L/min only	--
BiPAP	Either L/min or %	Convert % to L/min
CPAP	Either L/min or %	Convert % to L/min
Continuous mechanical – hospitalized	% only	Convert % to L/min
Continuous mechanical – not hospitalized	% only	Convert % to L/min
Intermittent mechanical – hospitalized	% only	Convert % to L/min
Intermittent mechanical – not hospitalized	% only	Convert % to L/min

High flow nasal cannula is distinct from other oxygen delivery devices in that it allows for separate titration of the flow rate in L/min and the FiO₂ in %. The Committee proposes collecting both the L/min and the % for candidates on high flow nasal cannula because entering only the L/min or the % does not accurately depict a candidate’s oxygen needs. For example, a patient could be on a very high flow rate in L/min but a low % FiO₂, and that patient’s overall oxygen requirements might be lower than a patient using a lower flow rate in L/min but 100% FiO₂. However, since the OPTN has not collected these data previously, the lung CAS does not account for the complexity of the interaction between flow rate and FiO₂ for patients on high flow nasal cannula. Accordingly, only one value can be used in the lung CAS calculation. The Committee proposes having the system convert the entered % value for high flow

³⁸ The conversion is 3% per liter, per minute after subtracting 21% (to account for room air). For example, 30% O₂ converts to 3 L/min: (30% - 21%) / 3% per L/min = 3 L/min.

devices to L/min, compare that value to the entered L/min, and then use whichever value is higher for the purposes of calculating the lung CAS. This is due to the Committee's preference not to disadvantage a candidate because of an absence of data on how varying high flow nasal cannula settings impact the mortality models. This approach will also standardize how supplemental oxygen information is incorporated into the lung CAS calculations for these patients, since lung transplant programs currently have the discretion to enter either the L/min or % for patients on high flow devices, and may or may not choose whichever value grants their candidate a higher score.

The Committee proposes not to include ECMO as a device that can be selected under the supplemental oxygen data collection, as the Committee's intent is not to capture ECMO device settings. For patients on ECMO, transplant programs would report the patients on ECMO under the assisted ventilation data collection, and use the supplemental oxygen data collection to report other devices used to deliver oxygen to the patient in addition to ECMO (e.g. continuous mechanical ventilation, nasal cannula, etc.). The supplemental oxygen data fields can be left blank if the patient is not using other oxygen delivery devices in addition to ECMO.

Prior Lung Surgery and Prior Cardiac Surgery

In public comment, the Committee proposed adding data collection on prior lung surgery and prior cardiac surgery in OPTN Waiting List. Prior lung surgery is currently collected on the TRR and prior cardiac surgery is currently collected on both the TRR and the TCR. Based on public comment feedback expressing concerns about data burden, and feedback from SRTR that current data collection on prior surgeries has not yielded data suitable for modeling, the Committee proposes making updates to the current data collection in Data System for Organ Procurement and Transplantation Network rather than adding data collection on prior surgeries in OPTN Waiting List. The Committee proposes collecting prior lung surgery and prior cardiac surgery on the TCR to capture the patient's history of thoracic surgery at the time of registration. The Committee proposes removing data collection on prior lung surgery and prior cardiac surgery from the TRR. The Committee intends for the proposed updates to the data collection to capture more granular information that may impact post-transplant outcomes.

In public comment, the Committee proposed adding data collection on pleurodesis in OPTN Waiting List. Following public comment, the Committee proposes capturing this information under the prior lung surgery data collection on the TCR.

Data Additions

The Committee proposes adding data collection on nine clinical criteria, summarized in **Table 4**, for which there is clinical literature to indicate that the criteria impact a candidate's waiting list survival or post-transplant outcomes. Three of these criteria would only apply to candidates with a diagnosis of pulmonary hypertension (indicated in the table as "PH diagnosis only"). The Committee strongly recommends that transplant programs update this information as needed as the patient's medical condition changes during their time on the waiting list, or at least every six months. The Committee also proposes including date fields with these criteria so that transplant programs can keep track of when they last updated their patients' information. The proposed data definitions at the end of the briefing paper indicate whether the date collected would be the test date or the evaluation date, where evaluation date refers to the date of the clinic visit at which the information was obtained.

Table 4: Proposed Additions

Clinical Criteria	Rationale
NYHA Functional Classification (PH diagnosis only)	This is a standard scale used for classifying the extent of heart failure based on patients' limitations during physical activity, and is commonly used for candidates with PH. ^{39,40,41,42}
Choose one: B-type Natriuretic Peptide (BNP) N-terminal prohormone BNP (NT-proBNP) (PH diagnosis only)	BNP and NT-proBNP "are released in response to changes in pressure inside the heart, [which] can be related to heart failure and other cardiac problems." ⁴³ Transplant programs frequently collect and track these data for PH patients and research suggest these criteria are prognostic indicators for mortality. ^{44,45}
Pericardial effusion (PH diagnosis only)	Research suggest that the presence of pericardial effusion in PH patients is a prognostic indicator for mortality. ^{46,47}
Massive hemoptysis, number of times in the last year	Clinical literature indicates that cystic fibrosis (CF) patients with a history of hemoptysis have increased mortality. ^{48,49,50,51,52,53}

³⁹ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, January 6, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/aj4dy11o/20220106_lung-umm-subcommittee-meeting-summary.pdf

⁴⁰ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, September 23, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/32ibu3sq/20210923_lung-umm-subcommittee-meeting-summary.pdf

⁴¹ New York Heart Association (NYHA) Classification, Specifications Manual for Joint Commission National Quality Measures (v2018A), accessed January 26, 2022, <https://manual.jointcommission.org/releases/TJC2018A/DataElem0439.html>

⁴² Benza et al. *The REVEAL Registry risk score calculator in patients newly diagnosed with pulmonary arterial hypertension*. *Chest* 2012; 141:354.

⁴³ "NT-proB-type Natriuretic Peptide," Cleveland Clinic, accessed June 12, 2022, <https://my.clevelandclinic.org/health/diagnostics/16814-nt-prob-type-natriuretic-peptide-bnp>.

⁴⁴ G. Warwick, P.S. Thomas, and D.H. Yates, "Biomarkers in pulmonary hypertension," *European Respiratory Journal* 32 (2008):503-512, DOI: 10.1183/09031936.00160307.

⁴⁵ Nazzareno Galie, Marc Humbert, and Jean-Luc Vachiery, et al., "2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension," *European Heart Journal* 37 no. 1 (2016):67-119, <https://doi.org/10.1093/eurheartj/ehv317>.

⁴⁶ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, September 23, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/32ibu3sq/20210923_lung-umm-subcommittee-meeting-summary.pdf

⁴⁷ Benza et al. *Predicting survival in pulmonary arterial hypertension: insights from the Registry to Evaluate Early and Long-Term Pulmonary Arterial Hypertension Disease Management (REVEAL)*. *Circulation*. 2010 Jul 13;122(2):164-72.

⁴⁸ Ibid.

⁴⁹ Lehr et al. *Effect of Including Important Clinical Variables on Accuracy of the Lung Allocation Score for Cystic Fibrosis and Chronic Obstructive Pulmonary Disease*. *Am J Respir Crit Care Med*. 2019 Oct 15;200(8):1013-1021.

⁵⁰ Clark et al. *Massive Hemoptysis in Cystic*. *Chest* 2005;128:729-38.

⁵¹ Flight et al. *Outcomes Following Bronchial Artery Embolisation for Haemoptysis in Cystic Fibrosis*. *Cardiovasc Intervent Radiol* 2017;40(8):1164-8.

⁵² Vidal et al. *Bronchial artery embolization in adults with cystic fibrosis: impact on the clinical course and survival*. *J Vasc Interv Radiol*. 2006 Jun;17 (6):953-8.

⁵³ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, February 3, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/3c4otx32/20220203_lung-umm-subcommittee-meeting-summary.pdf

Clinical Criteria	Rationale
Exacerbations, number of times in the last year	The occurrence of exacerbations is noted in clinical literature as a prognostic indicator, ^{54,55,56} and Committee members reported that in their experience, exacerbations tend to signal an inflection point of increased waitlist mortality. ⁵⁷ Exacerbations were also identified as a theme in Lung Review Board exceptions in that patients with exacerbations required increased inpatient and outpatient clinical intervention. The Committee proposes distinct data definitions for exacerbations for three diagnosis: chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), and cystic fibrosis (CF). ^{58,59,60,61}
Microbiology	Literature indicates that <i>Burkholderia cenocepacia</i> and <i>Mycobacterium abscessus</i> infections impact post-transplant morbidity. ^{62,63,64} Case studies report that <i>Burkholderia gladioli</i> ⁶⁵ and <i>Scedosporium/Pseudallescheria</i> species complex ⁶⁶ / <i>Lomentospora</i> may also be associated with post-transplant morbidity. The Committee proposes also including data collection in OPTN Waiting List that mirrors the <i>Pan-Resistant Bacterial Lung Infection</i> data collection on the Lung Transplant Candidate Registration (TCR).

⁵⁴ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, July 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/1a0lse5/20210722_lung-umm-subcommittee-meeting-summary.pdf

⁵⁵ Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report), accessed March 22, 2022, https://goldcopd.org/wp-content/uploads/2019/12/GOLD-2020-FINAL-ver1.2-03Dec19_WMV.pdf

⁵⁶ Lehr et al. *Effect of Including Important Clinical Variables on Accuracy of the Lung Allocation Score for Cystic Fibrosis and Chronic Obstructive Pulmonary Disease*. *Am J Respir Crit Care Med*. 2019 Oct 15;200(8):1013-1021.

⁵⁷ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, July 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/1a0lse5/20210722_lung-umm-subcommittee-meeting-summary.pdf

⁵⁸ Lung Transplantation Committee Meeting Summary, May 13, 2022, OPTN, accessed June 10, 2022, https://optn.transplant.hrsa.gov/media/uo1jchw4/20220513_lung-committee-meeting-summary.pdf.

⁵⁹ "Management of COPD exacerbations: a European Respiratory Society/American Thoracic Society guideline," *European Respiratory Journal* (2017): 1-16, DOI: 10.1183/13993003.00791-2016.

⁶⁰ Maya M. Juarez, Andrew L. Chan, and Andrew G. Norris, et al., "Acute exacerbation of idiopathic pulmonary fibrosis – a review of current and novel pharmacotherapies," *Journal of Thoracic Disease* 7 no. 3 (2015):499-519, doi: 10.3978/j.issn.2072-1439.2015.01.17.

⁶¹ P.A. Flume, P.J. Mogayzel Jr, and K.A. Robinson, et al., "Clinical Practice Guidelines for Pulmonary Therapies Committee. Cystic fibrosis pulmonary guidelines: treatment of pulmonary exacerbations." *American Journal of Respiratory and Critical Care Medicine* 180 no. 9 (2009):802-808. doi: 10.1164/rccm.200812-1845PP.

⁶² Huang HC, Weigt SS, Derhovanessian A, Palchevskiy V, Ardehali A, Saggarr R, Kubak B, Gregson A, Ross DJ, Lynch JP, 3rd, Elashoff R, Belperio JA. Nontuberculous mycobacterium infection after lung transplantation is associated with increased mortality. *The Journal of heart and lung transplantation : the official publication of the International Society for Heart Transplantation* 2011; 30(7): 790- 798

⁶³ Anthony De Soyza, Gerard Meachery, Katy L.M. Hester, Audrey Nicholson, Gareth Parry, Krzysztof Tocewicz, Thasee Pillay, Stephen Clark, James L. Lordan, Stephan Schueler, Andrew J. Fisher, John H. Dark, F. Kate Gould, Paul A. Corris, Lung transplantation for patients with cystic fibrosis and *Burkholderia cepacia* complex infection: A single-center experience, *The Journal of Heart and Lung Transplantation*, 2010: 29 (12): 1395-1404

⁶⁴ Hadjiliadis D, Steele MP, Chaparro C, Singer LG, Waddell TK, Hutcheon MA, Davis RD, Tullis DE, Palmer SM, Keshavjee S. Survival of lung transplant patients with cystic fibrosis harboring panresistant bacteria other than *Burkholderia cepacia*, compared with patients harboring sensitive bacteria. *J Heart Lung Transplant*. 2007 Aug;26(8):834-8. doi: 10.1016/j.healun.2007.05.018. Epub 2007 Jul 12. PMID: 17692788.

⁶⁵ Marcus P. Kennedy, Raymond D. Coakley, and Scott H. Donaldson et al, "Burkholderia gladioli: Five year experience in a cystic fibrosis and lung transplantation center," *Journal of Cystic Fibrosis* no. 6 (2007): 267-273.

⁶⁶ Florent Morio, Delphine Horeau-Langlard, and Françoise Gay-Andrieu, et al., "Disseminated *Scedosporium/Pseudallescheria* Infection after Double-Lung Transplantation in Patients with Cystic Fibrosis"

Clinical Criteria	Rationale
Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)	Transplant programs already capture DLCO as part of pulmonary function tests performed to enter other candidate data. DLCO assesses the severity of obstructive and restrictive lung diseases, pulmonary vascular disease, and preoperative risk. ^{67,68,69}
Mean Right Atrial Pressure (mRAP)	Transplant programs already capture mRAP as part of heart catheterization tests, and mRAP was identified as a mortality risk factor by the Registry to Evaluate Early and Long-term pulmonary arterial hypertension (PAH) Disease Management (REVEAL) report. ⁷⁰
Pulmonary Vascular Resistance (PVR)	Transplant programs already capture PVR as part of heart catheterization tests, and PVR was identified as a mortality risk factor by the Registry to Evaluate Early and Long-term PAH Disease Management (REVEAL) report. ⁷¹

Post-Public Comment Changes

In public comment, the Committee proposed collecting data on two additional clinical criteria: recurrent pneumothorax and bronchopleural fistula. Based on public comment feedback expressing concerns about data burden, and feedback from SRTR that the incidence of these conditions may be too low for the Committee to gather enough data to include them in the models, the Committee decided to remove these criteria from the proposed data collection. The Committee recommends that transplant programs continue to submit exception requests as needed for patients who are deemed to face increased waitlist mortality as a result of recurrent pneumothorax or bronchopleural fistula.

The proposed data additions are all criteria that are captured via the REVEAL registry for patients with pulmonary hypertension⁷² or the Cystic Fibrosis Foundation Patient Registry.⁷³ Based on public comment feedback recommending that the Committee consider more expedient approaches to incorporate additional data into the mortality models, the Committee has requested that the SRTR assess the feasibility of incorporating the data from these registries into the mortality models. If the SRTR determines it is feasible, then the Committee requests that the SRTR evaluate the impact of these criteria in the mortality models and whether these criteria should be included in the allocation score. Simultaneously, the Committee proposes that the OPTN move forward with collecting this data. Unlike the registries, the OPTN would be collecting these data on all lung candidates, rather than just candidates with pulmonary hypertension and cystic fibrosis, thereby expanding and strengthening the quality of the existing data. This dual approach is intended to reduce the timeframe for adding additional criteria to the mortality models as well as to ensure an equitable approach to assessing the

⁶⁷ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, September 23, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/32ibu3sq/20210923_lung-umm-subcommittee-meeting-summary.pdf

⁶⁸ Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, January 6, 2022, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/aj4dy11o/20220106_lung-umm-subcommittee-meeting-summary.pdf

⁶⁹ Modi, P. & Cascella, P., *Diffusing Capacity Of The Lungs For Carbon Monoxide*. StatPearls. March 24, 2021, accessed March 23, 2022, <https://www.ncbi.nlm.nih.gov/books/NBK556149/>

⁷⁰ Benza et al. *Predicting survival in pulmonary arterial hypertension: insights from the Registry to Evaluate Early and Long-Term Pulmonary Arterial Hypertension Disease Management (REVEAL)*. *Circulation*. 2010 Jul 13;122(2):164-72.

⁷¹ Ibid.

⁷² REVEAL Registry Risk Score 2.0 for Pulmonary Arterial Hypertension, accessed October 25, 2022, <https://www.mdcalc.com/calc/10071/reveal-registry-risk-score-pulmonary-arterial-hypertension-pah>

⁷³ Lehr, "Effect of Including Important Clinical Variables," 1014-1015.

impact of these criteria on the mortality of all lung candidates, and not just those patients with the diagnoses captured in the registries.

Policy Changes

The Committee proposes three policy changes: one change to add a new diagnosis code, and two changes related to data collection for supplemental oxygen.

First, the Committee proposes adding the diagnosis code for combined pulmonary fibrosis and emphysema (CPFE) to diagnosis group D in policy for the purposes of calculating the lung CAS, since candidates who requested exceptions based on this diagnosis were registered under the idiopathic pulmonary fibrosis (IPF) diagnosis code that falls in group D. These candidates would be assigned the coefficient for diagnosis group D for the calculation of their waiting list survival score, as indicated in *Table 21-3 Waiting List Survival Calculation: Covariates and their Coefficients* in OPTN policy, and for the post-transplant outcomes score, as indicated in *Table 21-6 Post-Transplant Outcomes Calculation: Covariates and Their Coefficients* in OPTN policy. The Committee reviewed the clinical narratives for patients with exception requests between January 1, 2019, and December 31, 2020, and found several exception requests for patients with CPFE citing literature that these patients have higher mortality than those with IPF.^{74,75,76,77} Furthermore, the American Thoracic Society recently released a joint statement with international thoracic societies recommending that CPFE be identified as a syndrome that warrants focused research.⁷⁸ Designating CPFE as a separate diagnosis code will allow the OPTN to collect data on this specific population of candidates and assess in the future whether they should be assigned a different coefficient based on their diagnosis, instead of the group D coefficient assigned to IPF candidates. In the absence of these data, including these candidates in group D is consistent with current practice to list IPF as their primary diagnosis.

The Committee proposes two additional policy changes to align with the proposed data collection changes for supplemental oxygen. These policy changes state how a patient's lung CAS will be calculated if the patient's oxygen requirements exceed what is accounted for in the lung CAS. Currently, the maximum value that can be entered for supplemental oxygen is 26.33 L/min, based on policy implemented in 2012.⁷⁹ If supplemental oxygen is entered as a percentage, a value of 100% is converted to a maximum L/min score of 26.33 L/min. This proposal would allow transplant programs to enter up to 100 L/min in this field to reflect the capacity of oxygen delivery devices currently in use. However, a maximum value of 26.33 L/min would be used to calculate the patient's allocation score. This is because the mortality models are currently based on a maximum value of 26.33 L/min for this covariate, so there is not adequate information on how to incorporate values above 26.33 L/min into the allocation score calculations. For example, while it might be appropriate to assign more points to a patient on 50 L/min of supplemental oxygen, the OPTN does not have data to determine if, and how many, more points should be assigned to that patient relative to a patient on 26.33 L/min of supplemental oxygen. Allowing transplant programs to enter values above 26.33 L/min will enable collection of these data for further

⁷⁴ Matthew D. Jankowich and Sharon I.S. Rounds, "Combined pulmonary fibrosis and emphysema syndrome: a review," *Chest* 141 no. 1 (2012): 222-231, DOI: 10.1378/chest.11-1062.

⁷⁵ Lijuan Zhang, Chunling Zhang, and Fushi Dong, et al., "Combined pulmonary fibrosis and emphysema: a retrospective analysis of clinical characteristics, treatment and prognosis," *BMC Pulmonary Medicine* 16 no. 1 (2016): 137, DOI: 10.1186/s12890-016-0300-7.

⁷⁶ An Zhao, Eyjolfur Gudmundsson, and Nesrin Mogulkoc, et al., "Mortality in CPFE patients is determined by the sum of pulmonary fibrosis and emphysema," *ERJ Open Research* 8 no. 2 (2021), DOI: 10.1183/23120541.00316-2021.

⁷⁷ Tomoo Kishaba, Yousuke Shimaoka, and Hajime Fukuyama, et al., "A cohort study of mortality predictors and characteristics of patients with combined pulmonary fibrosis and emphysema," *BMJ Open* 2(2012): e000988, DOI: 10.1136/bmjopen-2012-000988.

⁷⁸ Vincent Cottin, Moises Selman, Yoshikazu Inoue, et al., "Syndrome of Combined Pulmonary Fibrosis and Emphysema: An Official ATS/ERS/JRS/ALAT Research Statement," *American Journal of Respiratory and Critical Care Medicine* 206 no. 4 (2022):e7–e41, DOI: 10.1164/rccm.202206-1041ST.

⁷⁹ "Proposal to Revise the Lung Allocation Score (LAS) System," OPTN, 2012.

analysis. Accordingly, the Committee proposes a policy change to document this value substitution in OPTN Policy 21.2.A *Values Used in the Calculation of Lung Waiting List Survival*.

The second policy change related to supplemental oxygen applies to candidates on ECMO. Currently, there is not a way to indicate that a lung candidate is on ECMO via the data collection on assisted ventilation. ECMO is being added as an option to select under “assisted ventilation” in implementation of continuous distribution of lungs,⁸⁰ but in the absence of this option, the former OPTN Thoracic Organ Transplantation Committee⁸¹ offered guidance to transplant programs in 2013 for reporting data on lung candidates supported by ECMO. Specifically, the Committee advised that programs report the candidate’s assisted ventilation status as “continuous mechanical ventilation” and report the candidate’s supplemental oxygen as FiO₂ of 100%.⁸² Currently, the system converts the 100% FiO₂ score to a value of 26.33 L/min for the purposes of calculating the allocation score. Now that ECMO will be included as an option for “assisted ventilation,” the Committee wants to collect accurate data on supplemental oxygen for candidates supported by ECMO without negatively impacting the allocation scores for these candidates. Accordingly, the Committee proposes adding to policy that the system will assign the maximum value for the supplemental oxygen covariate for patients reported on ECMO under the assisted ventilation covariate. This will allow transplant programs to enter accurate data on their candidate’s oxygen needs while still giving candidates the appropriate allocation score based on their urgency status. Additionally, the Committee proposes a post-public comment change to clarify that for a candidate on ECMO, if their supplemental oxygen value expires but the assisted ventilation value indicating that they are on ECMO is still current, then the candidate still receives the maximum score for supplemental oxygen. However, if the candidate’s assisted ventilation value expires and the supplemental oxygen value is still current, then the candidate is no longer considered to be on ECMO and the entered value for supplemental oxygen at rest will be used in the allocation score calculation. The interaction between the assisted ventilation and supplemental oxygen data fields for candidates on ECMO is summarized in **Table 5**.

Table 5. Interaction of Assisted Ventilation and Supplemental Oxygen Fields for Candidates on ECMO

If the assisted ventilation value is:	And the supplemental oxygen value is:	Then the value used for supplemental oxygen in the candidate’s score is:
ECMO, not expired	Not expired	26.33 L/min (maximum score)
ECMO, expired	Not expired	The value entered for required supplemental oxygen “at rest”
ECMO, not expired	Expired	No supplemental oxygen needed at rest (least beneficial value)
ECMO, expired	Expired	No supplemental oxygen needed at rest (least beneficial value)

Data Collection Proposal Development

The Committee sought input and guidance from the OPTN Data Advisory Committee (DAC) during the development of this proposal to improve data quality and to ensure that proposed changes to OPTN data collection are aligned with the OPTN Principles for Data Collection.⁸³ The DAC is an operating

⁸⁰ “Establish Continuous Distribution of Lungs,” OPTN, Briefing Paper, accessed June 17, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

⁸¹ “Thoracic Committee,” OPTN, accessed November 1, 2022, <https://optn.transplant.hrsa.gov/about/committees/thoracic-committee/>.

⁸² “How to report data for lung transplant candidates supported by ECMO,” UNOS, accessed June 16, 2022, <https://unos.org/news/how-to-report-data-for-lung-transplant-candidates-supported-by-ecmo/>.

⁸³ “Principles for Data Collection,” OPTN, accessed June 12, 2022, <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>.

committee of the OPTN and oversees all data-related functions, including collaboration with other OPTN committees on modification, addition, and removal of data collected by the OPTN in order to improve the completeness, accuracy, and timeliness of the data.⁸⁴ Through discussion, the Committee evaluated the proposed data collection against a data quality checklist to ensure the quality, usefulness, transparency and reliability of OPTN data. This checklist is a tool to ensure a consistent and systematic approach to aid OPTN Committees in the assessment of data they seek to add, modify, or remove. The Committee presented their analysis to DAC, which evaluated the potential data burden of the proposal and endorsed the project.^{85,86} The Committee presented to DAC again following public comment and considered DAC's feedback before finalizing the proposal. The Committee incorporated some of DAC's feedback by making post-public comment changes to reduce the overall data burden of the proposal and to explore options for supplementing OPTN data collection with existing data sources.

Overall Sentiment from Public Comment

Committee members presented the proposal to all 11 OPTN regions and to three committees for feedback, and a video presentation describing the proposal was posted to the OPTN website. Four professional organizations as well as a transplant center and an individual respondent also provided written public comments. Most of the feedback supported the proposal, though a few respondents opposed the proposal and some supportive comments mentioned concerns. The proposal collected sentiment from 189 respondents, including 17 written comments. Sentiment is detailed below in **Figures 1 and 2**:

⁸⁴ OPTN Data Advisory Committee. <https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/>

⁸⁵ OPTN Data Advisory Committee, OPTN, Meeting Summary, September 13, 2021, accessed June 12, 2022, https://optn.transplant.hrsa.gov/media/h0lj2znt/20210913_dac_meeting_summary.pdf.

⁸⁶ OPTN Data Advisory Committee, OPTN, Meeting Summary, March 7, 2022, accessed October 6, 2022, https://optn.transplant.hrsa.gov/media/ejenwix0/20220307_optn_dac_meeting_summary.pdf.

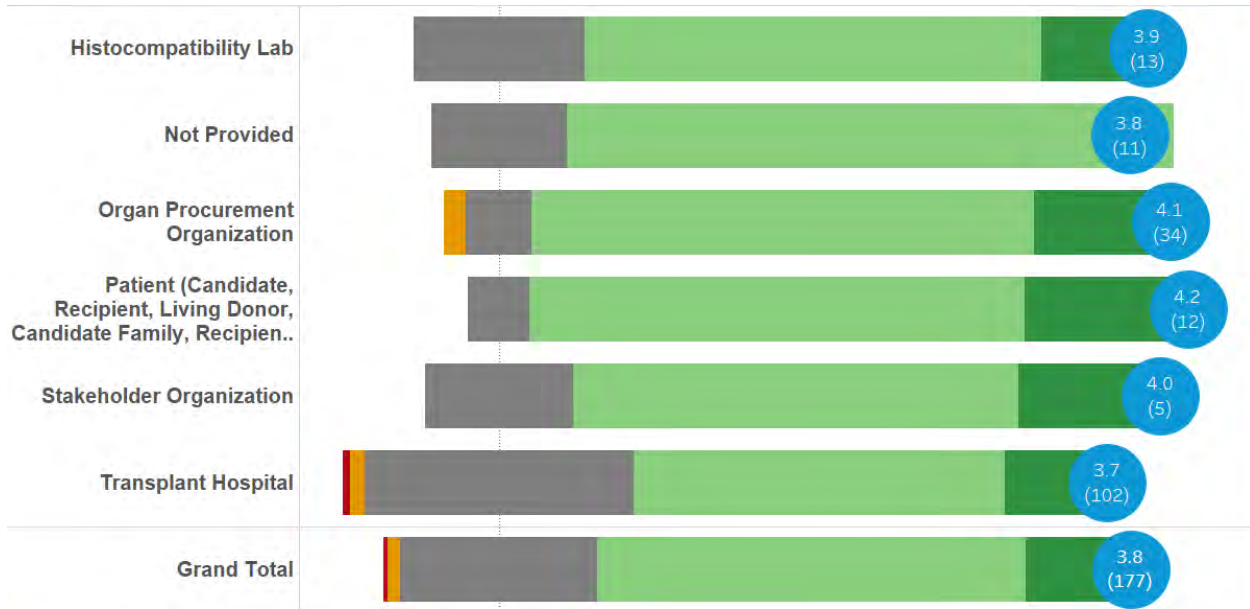
Figure 1: Regional Sentiment, Lung Mortality Models Proposal, 2022⁸⁷



The proposal was supported across the 11 regions overall, though one respondent in Region 10 indicated they opposed the proposal due to the additional work it would impose on transplant programs, and three respondents in Region 8 indicated they either opposed or strongly opposed the proposal, given that the proposed data collection would not be mandatory and it was unclear how long it would take to collect sufficient data.

⁸⁷ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 2: Sentiment by Member Type, Lung Mortality Models Proposal, 2022⁸⁸



Sentiment Intensity
 ■ Strongly Oppose
 ■ Oppose
 ■ Neutral/Abstain
 ■ Support
 ■ Strongly Support

The proposal was supported across member types, though one organ procurement organization (OPO) and three transplant hospitals indicated that they opposed or strongly opposed the proposal. The opposed sentiment from Region 10 was submitted by one of these transplant hospitals, and the remaining three sentiments that were opposed or strongly opposed were submitted by members in Region 8 (one OPO and two transplant hospitals).

Public comment feedback included general feedback on the Committee’s intent to collect additional data for the purposes of informing potential changes to the allocation score, and more specific feedback with suggested changes to the data fields and data definitions.

General Feedback on Data Collection

Many comments supported the proposal, noting that the proposed data additions will more accurately reflect the risks that patients encounter that are not currently captured in the allocation score. Comments supported using the additional data for a future project to improve the mortality estimates used in the allocation score.

Some comments expressed concern about the added burden on transplant programs to report additional data, noting that data integrity can suffer when the data burden is high, but many of these comments also acknowledged the value of the proposed data collection. Accordingly, many comments encouraged the Committee to monitor the data collection changes closely and to continue to remove data fields that do not factor into the allocation score or are otherwise not adding value. The Committee recognizes the concerns about data burden and sought to minimize burden as much as possible throughout the development of this proposal. Following public comment, the Committee further

⁸⁸ Ibid.

reduced the data burden by removing five of the criteria originally proposed to be collected in OPTN Waiting List (recurrent pneumothorax, bronchopleural fistula, pleurodesis, prior cardiac surgery, and prior lung surgery). The Committee also proposes updates to the data collection on prior lung surgery (including pleurodesis) and prior cardiac surgery in the Data System for OPTN, including removing this data collection from the TRR and updating the data collection on the TCR. The Committee will continue to look for opportunities to reduce data burden by eliminating data collection that is no longer needed.

Two comments said that the proposed data additions should be required fields since the intent is to model the data to determine whether those criteria should be incorporated into the allocation score. Similarly, the DAC suggested that the Committee consider requiring the data collection to avoid “cherry picking” of data, and to consider a pilot project to determine which data are important before requiring it. Three other comments expressed concern that leaving the data collection as optional could make it subject to reporting bias. The Committee considered multiple options for collecting these data and notes there is strong evidence that the proposed data additions are for criteria that impact patient mortality. Accordingly, the Committee did not think that a pilot project would be a good use of resources. The proposed data additions in OPTN Waiting List would not be required fields because almost all of the data collection in OPTN Waiting List for lung candidates are not required fields, including the fields that impact the allocation score. Since OPTN policy outlines the values that will be substituted in the allocation score for missing or expired data, those fields are not required. The Committee determined that it would be inappropriate to require data entry for the proposed data additions, which will not impact the allocation score at this time, since that would be inconsistent with current data collection for criteria that do impact the allocation score. However, the Committee decided following public comment that two criteria, prior lung surgery and prior cardiac surgery, would be collected on the TCR rather than OPTN Waiting List, and fields on the TCR are required. The Committee did not support that approach for the other criteria because the goal is for transplant programs to continue to update those fields while their patients are on the waiting list to capture changes in the patients’ conditions over time. OPTN Waiting List is more suitable for this type of data collection since transplant programs must keep it up to date, whereas information submitted in TCR is intended to reflect a candidate’s condition at the time of registration.

Two comments requested that SRTR provide an analysis of how long it would take to collect sufficient data to update the mortality models, and that the Committee consider alternate options for data collection if it will take longer than one to two years. SRTR estimates that at least two years of follow-up data collection would be needed in order to consider refitting the model. However, SRTR will also evaluate the feasibility of using registry data in combination with OPTN data to refit the model sooner.

Two comments suggested that the Committee explore the possibility of leveraging electronic health records (EHRs) for retrospective data collection to collect the desired information more quickly. Similarly, another comment asked that the OPTN work with EHR vendors to establish functioning application programming interfaces (APIs) to facilitate data transfer with less burden on transplant hospitals. The Committee notes that implementation of this proposal would include making updates to OPTN APIs. However, transplant hospitals must also work with their EHR vendors to make updates to their systems, and as of October 2022, no lung transplant programs have integrated with existing OPTN Waiting List APIs. One comment noted that the OPTN previously used retrospective data collection to inform development of the lung allocation score. This was a resource-intensive effort that involved training OPTN staff to review medical records, and a similar effort would be out of scope for this proposal. Current OPTN APIs are not designed for retrospective data collection and cannot “pull” data, as information must still be “pushed” by the transplant hospital. Accordingly, it is more expedient for the Committee to collect data via OPTN Waiting List and to explore analysis of existing data sources than

for the OPTN, transplant hospitals, and EHR vendors to develop the infrastructure required to facilitate retrospective data transfer. The Committee supports further efforts by the OPTN to facilitate data acquisition for the purposes of developing allocation policies. In the interim, the Committee proposes moving forward with this proposal to begin collecting these important data.

One comment recommended providing education on the data collection changes to ensure that transplant programs maintain the appropriate supporting clinical documentation. The Committee agrees and will provide educational resources to support implementation of this proposal.

Specific Feedback on Data Fields and Data Definitions

Comments included suggestions for changes to the proposed data collection on exacerbations, microbiology, assisted ventilation, supplemental oxygen, and prior surgeries. Comments also provided suggestions for additional data that should be collected or removed.

Exacerbations

Two comments suggested including a definition of exacerbations for candidates with pulmonary arterial hypertension as these candidates may have recurrent hospital admissions due to right heart failure. The Committee holds that this represents progression of disease rather than an exacerbation and did not incorporate this change into the data definition.

A comment noted that the need for hospitalization might be a marker for more serious deterioration and should be included in the definitions of exacerbations for COPD and CF. Alternatively, the commenter suggested collecting the number of exacerbations that required hospitalization in the last year, as well as the total number of exacerbations. One comment suggested adding something to the definition such as “treatment required” as there is concern that transplant programs may game the system by listing patients as having an exacerbation so that they can acquire a higher allocation score. The Committee considered several different approaches for capturing exacerbations and thought that distinguishing between exacerbations that required hospitalization and those that did not require hospitalization may compromise data integrity, particularly for patients who cannot be discharged from the hospital. Additionally, the disease-specific definitions refer to requiring treatment or the need for hospitalization.

Two comments said that the definitions for exacerbations should be more detailed, less subjective, and evidence-based. The Committee notes that these definitions were derived from clinical guidelines issued by thoracic professional societies, and the Committee requested public comment feedback on other clinical parameters that should be incorporated into these definitions.

Microbiology

The OPTN Disease Transmission Advisory Committee (DTAC) recommended adding *Lomentospora* under reportable multi-drug resistant organisms due to a change in nomenclature. DTAC expressed concern about the organisms selected, noting that as far as fungal infections, there are not specific data to favor the organisms listed. DTAC suggested modifying the list of options to reflect groups of organisms so that it is less specific. The Committee adopted DTAC’s recommended definition for multi-drug resistant organisms and added *Lomentospora* as an option to the dropdown list along with *Scedosporium/Pseudallescheria* species complex.

Assisted Ventilation

A comment noted that patients who have been on ECMO for weeks have worse post-transplant outcomes than someone who is only on ECMO for a few days. The Committee appreciates this feedback but does not intend to collect data on time on ECMO at this time.

A comment said that the choice not to capture ECMO device settings is reasonable and noted that use of venoarterial (VA) or venovenous (VV) ECMO may reflect center level practices in addition to reflecting patient severity.

Supplemental Oxygen

A comment suggested defining the machine being used for supplemental oxygen since FiO₂ varies based on the machine being used. The Committee agrees and this is part of the proposed data collection.

A comment said it would be helpful to understand how the use of different oxygen delivery devices may adjust their LAS and future CAS, especially in the case of individuals who require a converted oxygen requirement of >26.3 L. Currently, whether or not a candidate is on continuous mechanical ventilation-hospitalized impacts a candidate's lung allocation score. The Committee expects that further data collection and modeling regarding supplemental oxygen needs by oxygen delivery device may yield additional stratifications in candidate medical urgency that may be appropriate to include in the allocation score.

A comment noted that with the varying type of oxygen machines and delivery devices that are currently on the market, standardization cannot be guaranteed across institutions or providers, so it may be best to use the fractionated oxygen percentage and not the flow by liter per minute to promote standardization. The Committee holds that entering oxygen needs in L/min is more appropriate for some oxygen delivery devices as outlined in **Table 3**.

For patients on high flow nasal cannula, a comment suggested that it would be better to directly calculate the true oxygen flow rate by multiplying the flow rate and the calculated flow rate based on FiO₂, rather than using the higher value of the two. The Committee did not think that this approach would appropriately capture supplemental oxygen needs for adult lung candidates and proposes using the most beneficial value for candidates on high flow nasal cannula.

Diffusing Capacity of Lungs for Carbon Monoxide

A comment noted that DLCO data could be difficult to use if not corrected for hemoglobin, since the data could have a lot of variability that would not necessarily reflect severity. Another comment agreed that it would be important to collect DLCO values corrected for hemoglobin as well as for alveolar volume. The Committee considered this feedback and noted that some transplant programs collect hemoglobin on the same day that they conduct the DLCO data and some transplant programs do not. Accordingly, the Committee determined it is most appropriate to collect the uncorrected DLCO data so that it is entered consistently, and added this clarification to the data definition.

Prior Surgeries

A comment noted that video-assisted thoracic surgery (VATS) is a technique, not a type of operation, and recommended modifying the data collection to indicate whether each of the surgery was performed via VATS or open (e.g. VATS lobectomy vs. open lobectomy). The Committee agrees and updated the data collection options to remove references to surgical technique.

Data Additions

Recommendations for additional data collection included:

- Requiring more frequent updates to clinical data for patients with higher allocation scores since they are a very different population from the patients with lower allocation scores
- Simple measures of frailty that may predict waiting list mortality post-transplant mortality
- Immunodeficiency, such as hypogammaglobulinemia, or if a patient has undergone an allogeneic stem cell transplant prior, as the community is seeing more interstitial lung disease (ILD) related transplants regarding mixed connective tissue disease or connective tissue disease
- Elements to assess pre- and post-mortality for elderly lung candidates, including donor characteristics

The Committee will consider this feedback for future projects.

Data Removal

One comment recommended removing age as a determinant to transplant due to personal experience of their late spouse being denied consideration for lung transplant at age 74 following severe pneumonia/COVID protocol treatments. The Committee notes that each transplant program determines its own listing criteria, and age is incorporated into the mortality models because it has been shown to be predictive of waiting list mortality and post-transplant outcomes.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to “establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria.”⁸⁹ The OPTN Final Rule states that the OPTN “shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”⁹⁰ This proposal would update the medical criteria for which data is collected on potential transplant recipients, which is expected to inform future updates to policies for allocation of lungs.

Additionally, the OPTN Final Rule states that the OPTN shall “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” and “maintain records of all transplant candidates, all organ donors and all transplant recipients.”⁹¹ The Final Rule also requires OPOs and transplant hospitals “as specified from time to time by the Secretary, to submit to the OPTN...information regarding transplantation candidates, transplant recipients, [and] donors of organs...”⁹² This proposal would update the information collected on lung transplant candidates to improve the models used to assign scores to candidates in lung allocation.

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

⁸⁹ 42 USC §274(b)(2)(B).

⁹⁰ 42 CFR §121.4(a)(1).

⁹¹ 42 C.F.R §121.11(a)(1)(i)-(ii).

⁹² 42 CFR § 121.11(b)(2).

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.”⁹³

This proposal:

- **Is based on sound medical judgment**⁹⁴ because it is an evidenced-based change relying on clinical literature, analysis of exception requests received by the Lung Review Board, and clinical experience regarding medical treatments, symptoms, and diagnoses that may impact a patient’s expected waiting list survival or post-transplant outcomes.
- **Seeks to achieve the best use of donated organs**⁹⁵ by ensuring organs are allocated and transplanted according to medical urgency. Specifically, the Committee proposes collecting data expected to better capture the expected waiting list survival of patients for whom the lung CAS may underestimate their urgency for transplant.
- **Is designed to avoid futile transplants**⁹⁶: This proposal should not result in transplanting patients that are unlikely to have good post-transplant outcomes, as it intends to collect data to improve estimates of a patient’s post-transplant outcomes. The lung CAS gives more points to patients who are expected to have better post-transplant outcomes.
- **Is designed to... promote patient access to transplantation**⁹⁷ by giving similarly situated candidates equitable opportunities to receive an organ offer. For example, adding the diagnosis code for CPFE will aid the Committee in determining whether it is appropriate to assign patients with CPFE the same points for diagnosis as IPF candidates, or if CPFE patients are more similar to patients with a different diagnosis and warrant a different number of points.
- **Is not based on the candidate’s place of residence or place of listing.**⁹⁸

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,⁹⁹ and it is specific to an organ type, in this case lung.¹⁰⁰

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Designed to avoid wasting organs¹⁰¹
- Promotes the efficient management of organ placement¹⁰²

Transition Plan

The Final Rule also requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies” whenever organ allocation policies are revised.¹⁰³ The Committee did not identify any populations that may be treated “less favorably than they would have been treated under the previous policies” if these

⁹³ 42 CFR §121.8(a).

⁹⁴ 42 CFR §121.8(a)(1).

⁹⁵ 42 CFR §121.8(a)(2).

⁹⁶ Id.

⁹⁷ Id.

⁹⁸ 42 CFR §121.8(a)(8).

⁹⁹ 42 CFR §121.8(a)(3).

¹⁰⁰ 42 CFR §121.8(a)(4).

¹⁰¹ 42 CFR §121.8(a)(5).

¹⁰² Id.

¹⁰³ 42 CFR § 121.8(d).

proposed policies are approved by the Board of Directors, as the proposed policy changes are intended to preserve the allocation priority that candidates on ECMO and high flow devices receive based on current data collection while the OPTN gathers additional data that better informs how these candidates should be prioritized.

OPTN Strategic Plan

Updating data collection on the disease severity of lung candidates aligns with the OPTN strategic plan goal to improve waitlisted patient, living donor, and transplant recipient outcomes. The proposed data collection changes are intended to improve the predictive ability of the mortality models used to calculate allocation scores for lung transplant candidates to better prioritize candidates for transplant.

Implementation Considerations

Lung transplant programs and the OPTN would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Transplant Programs

Operational Considerations

Lung transplant programs would need to become familiar with the changes to data collection for lung transplant candidates. Most of the current and proposed data collection for lung candidates in OPTN Waiting List is not required, as OPTN policy outlines the values that will be substituted in the allocation score for missing or expired data. Accordingly, the Committee proposes that the data additions should also not be required fields for consistency, particularly since they are not yet incorporated into the allocation score. However, the Committee recommends that transplant programs submit this data in order to inform future modeling.

Fiscal Impact

The proposal is not expected to have a substantial fiscal impact on transplant programs. New or additional resources may be needed to accommodate programming and staff training, but no additional staff, or extended hours for existing staff, are expected. Ongoing costs following implementation are expected to be minimal, and related to the increased data collection effort. Additionally, failing to implement the proposal could result in missed opportunities to further improve lung allocation.

OPTN

Operational Considerations

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN or collected in a different format. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, the modifications to the data collection may be submitted for OMB approval under the Paperwork Reduction Act of 1995.

The proposal *Establish Continuous Distribution of Lungs* is slated for implementation in early 2023,¹⁰⁴ and will include updates on data collection in OPTN Waiting List regarding ECMO status and type of

¹⁰⁴ "Establish Continuous Distribution of Lungs," OPTN, Briefing Paper, accessed May 26, 2022, <https://optn.transplant.hrsa.gov/media/esjb4ztn/20211206-bp-lung-establish-cont-dist-lungs.pdf>.

assisted ventilation. Specifically, ECMO will be added as an option under for “assisted ventilation.” This proposal to update data collection for lung mortality models builds upon that data collection by allowing programs to specify whether the candidates are on VA or VV ECMO, since these populations of candidates may have different disease severity, as well as indicating whether or not the candidates are also mechanically ventilated.

Resource Estimates

The OPTN contractor estimates 4,325 hours for implementation. Implementation will involve updates to the OPTN Computer System to build upon the changes from the previously approved *Establish Continuous Distribution of Lungs* effort, education and training on the changes, and communication efforts about the changes. The OPTN contractor estimates 270 hours for ongoing support. Ongoing support will involve answering member questions and monitoring post-implementation at 6 months, and then annually, for 2 to 3 years, as the Committee sees fit.

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.”¹⁰⁵ The OPTN will continue to review deceased donor match runs that result in a transplanted organ to ensure that organs have been allocated according to OPTN policy and will continue to investigate potential policy violations. During site surveys of transplant hospitals, the OPTN will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System are consistent with source documentation available at the time of entry.

Policy Evaluation

This proposal is designed to update data collection in the OPTN Waiting List related to disease severity of lung candidates by removing, revising, and adding data collection. A summary of the revised and additional data collection, including monitoring their use, will be provided to the Committee following implementation of the OPTN Waiting List changes. Summaries of the revised and new data collection will be provided at approximately 6 months after implementation, and then annually thereafter for 2-3 years as the Committee sees fit.

Conclusion

This proposal would update data collection related to disease severity of lung candidates by removing, revising, and adding data collection. The Committee would use these data to evaluate whether to update the mortality models used to calculate the waiting list survival and post-transplant outcome components of the lung composite allocation score. In response to public comment feedback, this proposal was updated to reduce the overall data burden on transplant programs, and to explore supplementing OPTN data collection with existing registry data in order to update the models more expediently.

¹⁰⁵ 42 CFR §121.8(a)(7).

Policy Language

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

1 10.1.F Lung Disease Diagnosis Groups

2 Each candidate is assigned a diagnosis group, based on their lung disease diagnosis, which is
3 used in the calculation of their medical urgency score and their post-transplant survival score.
4 [...]

5 **Group D**

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

- 7
- 8 • ABCA3 transporter mutation
- 9 • Alveolar proteinosis
- 10 • Amyloidosis
- 11 • Acute respiratory distress syndrome or pneumonia
- 12 • Bronchioloalveolar carcinoma (BAC)
- 13 • Carcinoid tumorlets
- 14 • Chronic pneumonitis of infancy
- 15 • Combined pulmonary fibrosis and emphysema (CPFE)
- 16 • Constrictive bronchiolitis
- 17 • COVID-19: acute respiratory distress syndrome
- 18 • COVID-19: pulmonary fibrosis
- 19 • CREST – Restrictive
- 20 • Eosinophilic granuloma
- 21 • Fibrosing Mediastinitis
- 22 • Graft versus host disease (GVHD)
- 23 • Hermansky Pudlak syndrome
- 24 • Hypersensitivity pneumonitis
- 25 • Idiopathic interstitial pneumonia, with at least one of the following disease entities:
 - 26 ○ Acute interstitial pneumonia
 - 27 ○ Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia
 - 28 ○ (BOOP)
 - 29 ○ Desquamative interstitial pneumonia
 - 30 ○ Idiopathic pulmonary fibrosis (IPF)
 - 31 ○ Nonspecific interstitial pneumonia
 - 32 ○ Lymphocytic interstitial pneumonia (LIP)
 - 33 ○ Respiratory bronchiolitis-associated interstitial lung disease
 - 34 • Idiopathic pulmonary hemosiderosis
 - 35 • Lung retransplant or graft failure: acute rejection
 - 36 • Lung retransplant or graft failure: non-specific
 - 37 • Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
 - 38 • Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
 - 39 • Lung retransplant or graft failure: obstructive
 - 40 • Lung retransplant or graft failure: other specify

- 41 • Lung retransplant or graft failure: primary graft failure
- 42 • Lung retransplant or graft failure: restrictive
- 43 • Lupus
- 44 • Mixed connective tissue disease
- 45 • Obliterative bronchiolitis: non-retransplant
- 46 • Occupational lung disease: other specify
- 47 • Paraneoplastic pemphigus associated Castleman’s disease
- 48 • Polymyositis
- 49 • Pulmonary fibrosis: other specify cause
- 50 • Pulmonary hyalinizing granuloma
- 51 • Pulmonary lymphangiectasia (PL)
- 52 • Pulmonary telangiectasia – restrictive
- 53 • Rheumatoid disease
- 54 • Sarcoidosis with PA mean pressure greater than 30 mm Hg
- 55 • Scleroderma – restrictive
- 56 • Silicosis
- 57 • Sjogren’s syndrome
- 58 • Surfactant protein B deficiency
- 59 • Surfactant protein C deficiency
- 60 • Teratoma
- 61 • Wegener’s granuloma – restrictive
- 62

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

[...]

If values for certain covariates are missing, expired, or ~~below~~outside the threshold as defined by *Table 21-4*, 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: Substituted Values in Calculating Waiting List Survival Score* lists the ~~normal and least beneficial~~ values that will be substituted.

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

If this covariate’s value:	Is:	Then the waiting list survival calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
Height or weight to determine body mass index (BMI)	Missing	100 kg/m ²
Weight to determine BMI	Expired	100 kg/m ²

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
<u>Assisted ventilation</u>	<u>ECMO, and not expired</u>	<u>26.33L/min needed at rest for the "amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)" covariate</u>
Assisted ventilation	Missing or expired	No mechanical ventilation
Creatinine (serum) (mg/dL)	Missing or expired	0.1 mg/dL
Functional status	Missing or expired	No assistance needed
<u>Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)</u>	<u>Greater than 26.33 L/min at rest, and not expired</u>	<u>26.33L/min needed at rest</u>
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Missing or expired	No supplemental oxygen needed at rest
PCO ₂	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
Six-minute-walk distance	Missing or expired	4,000 feet

75 [...]

76 **21.2.B.1 Coefficients Used in Calculating Lung Post-Transplant**
 77 **Outcomes**

78 [...]

79 If values for certain covariates are missing, expired, or ~~below~~outside the threshold as defined by
 80 ~~Table 10-421-7~~, then the composite allocation score calculation will substitute ~~normal or least~~
 81 ~~beneficial~~ values to calculate the candidate's post-transplant outcomes score. ~~Table 21-7: Values~~
 82 ~~Substituted~~ Values for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes
 83 ~~Score~~ lists the ~~normal and least beneficial~~ values that will be substituted.

84
85

Table 21-7: Values-Substituted Values for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes Score

If this covariate's value:	Is:	Then the post-transplant outcomes score calculation will use this substituted value:
Cardiac index	Missing, or greater than 5	5.0 L/min/m ²
Assisted ventilation	Missing or expired	Continuous mechanical ventilation while hospitalized
Creatinine (serum) (mg/dL)	Missing, expired or greater than 1.6	1.6 mg/dL
Functional status	Missing or expired	Total assistance needed
Six-minute-walk distance	Missing or expired	200 feet
	Greater than 1,600	1,600 feet

#

Proposed Changes to Data Collection

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

Data Removals: Lung OPTN Waiting List

Clinical Criteria	Values	Recommended Changes & Comments
Percent Predicted FVC	Calculated %	Remove from the OPTN Waiting List
Post Bronchodilator Actual FEV ₁	Actual %	Remove from the OPTN Waiting List
Pre Bronchodilator Percent Predicted FEV ₁	Calculated %	Remove from the OPTN Waiting List
Post Bronchodilator Percent Predicted FEV ₁	Calculated %	Remove from the OPTN Waiting List
Requires Supplemental O2: How was the value obtained	Calculated from formula Read from oxygen delivery device	Remove from the OPTN Waiting List

Data Revisions: Lung OPTN Waiting List

Clinical Criteria	Values	Recommended Changes & Comments
Lung Diagnosis Code	Combined Pulmonary Fibrosis and Emphysema (CPFE)	Add this diagnosis code to options under existing data collection for “Lung Diagnosis Code” Diagnosis code will be assigned the coefficient for diagnosis group D for the purposes of calculating the lung CAS.
Diabetes	Current selection options: Dependency unknown Insulin dependent Not diabetic Not insulin dependent	Revise selection options to: Treated with insulin Not treated with insulin Not diabetic

Clinical Criteria	Values	Recommended Changes & Comments
Assisted Ventilation	<p>Current selection options: BiPAP CPAP Continuous mechanical – hospitalized Continuous mechanical – not hospitalized ECMO Intermittent mechanical No assisted ventilation needed</p>	<p>Revise selection options to: BiPAP CPAP Continuous mechanical – hospitalized Continuous mechanical – not hospitalized ECMO VA – mechanically ventilated VA – not mechanically ventilated VV – mechanically ventilated VV – not mechanically ventilated Intermittent mechanical – hospitalized Intermittent mechanical – not hospitalized No assisted ventilation needed</p>
Requires Supplemental O ₂	<p>Current selection options with the ability to enter one with one evaluation date: At rest At night With exercise only</p> <p>Current units: Max of 26.33 L/min</p>	<p>Revise selection options to allow for multiple entries and add evaluation dates for all three: At rest With exercise With sleep</p> <p>Proposed units: Max of 100 L/min</p> <p>Add device selection options: High flow nasal cannula (L/min and %) Nasal cannula (L/min only) Reservoir cannula (L/min only) Face mask (% only) BiPAP (Either L/min or %) CPAP (Either L/min or %) Continuous mechanical – hospitalized (% only) Continuous mechanical – not hospitalized (% only) Intermittent mechanical – hospitalized (% only) Intermittent mechanical – not hospitalized (% only)</p>
Six Minute Walk Distance	Integer value (no change)	Moved field to be below <i>Requires Supplemental O₂</i> for better flow of data entry

Data Changes: Lung Data System for OPTN

Clinical Criteria	Values	Recommended Changes & Comments
Prior Lung Surgery	Current selection options (TRR): Pneumoreduction Pneumothorax Surgery-Nodule Pneumothorax Decortication Lobectomy Pneumonectomy Left Thoracotomy Right Thoracotomy Other, specify	Remove from TRR; add to TCR with revised selection options (can select more than one) Selection options: None Left, Right Prior lung transplant Pneumonectomy Lung Volume Reduction Surgery Wedge Resection Lobectomy Pleural procedures Decortication Pleurectomy Pleurodesis Chemical Mechanical Talc Other, specify (with free text)
Prior Cardiac Surgery	Current selection options (TCR and TRR): CABG Valve Replacement/Repair Congenital Left Ventricular Modeling Other, specify	Remove from TRR and update selection options on the TRR (can select more than one) Selection options: None Sternotomy CABG Congenital Maze Valve replacement Other, specify (with free text)

Data Additions: Lung OPTN Waiting List

Clinical Criteria	Values	Recommended Changes & Comments
NYHA Functional Classification (PH Diagnosis Only)	Class I, Class II, Class III, Class IV	Add to the OPTN Waiting List

Clinical Criteria	Values	Recommended Changes & Comments
Choose one: BNP NT-proBNP (PH Diagnosis Only)	pg/mL or ng/L	Add to the OPTN Waiting List
Pericardial effusion (PH Diagnosis Only)	Yes, No	Add to the OPTN Waiting List
Massive hemoptysis, number of times in the last year	Free text integer number	Add to the OPTN Waiting List
Exacerbations, number of times in the last year	Free text integer number Check box to indicate if candidate has been on continuous intravenous antibiotics for longer than 60 days in the last year	Add to the OPTN Waiting List
Microbiology	Selection options: None Burkholderia cenocepacia (genomovar III) ≤ 1 year Burkholderia cenocepacia (genomovar III) > 1 year ago Burkholderia gladioli ≤ 1 year Burkholderia gladioli > 1 year ago MDR or Pan-R gram negative bacteria ≤ 1 year MDR or Pan-R gram negative bacteria > 1 year ago Mycobacterium abscessus ≤ 1 year Mycobacterium abscessus > 1 year ago Scedosporium/Pseudallescheria species Complex/Lomentospora ≤ 1 year Scedosporium/Pseudallescheria species Complex/Lomentospora > 1 year ago	Add to the OPTN Waiting List with option to select more than one
Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)	mL/min/mmHg Too sick to perform DLCO test? Yes/No	Add to the OPTN Waiting List as part of the pulmonary function test data section
Mean Right Atrial Pressure (mRAP)	mmHg	Add to the OPTN Waiting List as part of the most recent heart catheterization data section
Pulmonary Vascular Resistance (PVR)	dynes/sec/cm ⁵ or Wood units (mmHg/L/min)	Add to the OPTN Waiting List as part of the most recent heart catheterization data section

Serial Data Collection: Lung OPTN Waiting List

Clinical Criteria <i>Six-month prior to listing data</i>	Values	Recommended Changes & Comments
Actual Forced Vital Capacity (FVC)	Liters (L)	These data are currently collected in the OPTN Waiting List. The Committee proposes expanding this data collection to allow programs to enter values for multiple dates, including six months prior to listing.
Pre Bronchodilator Actual FEV1	Liters (L)	These data are currently collected in the OPTN Waiting List. The Committee proposes expanding this data collection to allow programs to enter values for multiple dates, including six months prior to listing.
Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)	mL/min/mmHg Too sick to perform DLCO test? Yes/No	These data are not currently collected in the OPTN Waiting List, so the Committee proposes adding this data collection and allowing programs to enter values for multiple dates, including six months prior to listing.

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Appendix A: Proposed Data Definitions

Lung OPTN Waiting List

Assisted Ventilation: Indicate the type of assisted ventilation the candidate requires. If the candidate does not require assisted ventilation, select **No assisted ventilation needed**. These fields must be updated every 6 months from the time the candidate was added to the Waitlist. If the fields are incomplete or the evaluation date has expired, the least beneficial value will be used to calculate the candidate's lung allocation score. Use of average volume-assured pressure support (AVAPS) should be reported as **intermittent mechanical**.

BNP or NT-proBNP: Enter the candidate's BNP or NT-proBNP lab values in pg/mL or ng/mL.

Definition: BNP (B-type natriuretic peptide) and NT-proBNP (N-terminal pro-BNP) are fragments cleaved from proBNP (pro B-type natriuretic peptide) that is secreted by cardiomyocytes in response to stretch.¹⁰⁶

Test Date: Enter the date when this information was obtained.

Diabetes: If the candidate has diabetes, select the option to indicate insulin dependency. If the candidate does not have diabetes, select **Not Diabetic**. A patient should *not* be considered as having diabetes based on a diagnosis of gestational diabetes only.¹⁰⁷

Treated with insulin

Not treated with insulin

Not diabetic

Eval Date: Enter the date when this information was obtained.

Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO): Enter the value of the diffusing capacity of the lungs for carbon monoxide in mL/min/mmHg, obtained from a pulmonary function test. Do not enter values corrected for hemoglobin or alveolar volume. If the patient cannot perform this test due to their medical status, select **Yes** for "Too sick to perform DLCO test?"

Definition: Diffusing capacity of the lungs for carbon monoxide is a measurement to assess the lungs' ability to transfer gas from inspired air to the bloodstream.¹⁰⁸

Test Date: Enter the date when this information was obtained.

Exacerbations, number of times in the last year: Enter the number of times within the last year from the date of entry that the patient has experienced an exacerbation. Select checkbox if patient has been on continuous intravenous antibiotics for longer than 60 days in the last year.

¹⁰⁶ Rasmus Rørth, Pardeep S. Jhund, Mehmet B. Yilmaz, et al., "Comparison of BNP and NP-proBNP in Patients With Heart Failure and Reduced Ejection Fraction," *Circulation: Heart Failure* 13 (2020): e006541, <https://doi.org/10.1161/CIRCHEARTFAILURE.119.006541>.

¹⁰⁷ Proposed data definition is based on the current data definition on the Lung Candidate Record in OPTN Waiting List, with modifications to reflect proposed changes to data collection.

¹⁰⁸ Pranav Modi and Marco Cascella, "Diffusing Capacity of the Lungs for Carbon Monoxide," *StatPearls* (2022) <https://pubmed.ncbi.nlm.nih.gov/32310609/>.

Definition: For patients with a diagnosis of chronic obstructive pulmonary disease (COPD), exacerbations are episodes of increasing respiratory symptoms that required treatment, particularly dyspnea, cough, and sputum production, and increased sputum purulence.¹⁰⁹

For patients with a diagnosis of interstitial lung disease (ILD), exacerbations are a sudden acceleration of the disease or an idiopathic acute injury superimposed on diseased lung that leads to a significant decline in lung function, acute increased need for oxygen, or need for hospitalization.¹¹⁰

For patients with a diagnosis of cystic fibrosis, exacerbations are a general increase in respiratory symptoms that required treatment accompanied by an acute decrease in lung function.¹¹¹

Eval Date: Enter the date when this information was obtained.

Massive hemoptysis, number of times in the last year: If the patient has experienced massive hemoptysis in the last year, enter the number of times experienced.

Definition: Hemoptysis is the coughing up of blood or bloody sputum from the lungs or airway. For adult patients, massive hemoptysis is defined as acute bleeding of ≥ 240 mL in a 24 hour period or recurrent bleeding of >100 mL each day for more than two days.¹¹² For pediatric patients, massive hemoptysis is defined as acute bleeding of ≥ 8 mL/kg at once or recurrent bleeding over several days equaling 8 mL/kg or more.¹¹³

Eval Date: Enter the date when this information was obtained.

Mean Right Atrial Pressure (mRAP): Enter the patient's mean right atrial pressure in mmHg. The mean should be calculated from measurements taken by right heart catheterization within the last year.

Definition: Right atrial pressure refers to blood pressure in the right atrium of the heart.¹¹⁴

Test Date: Enter the date when this information was obtained.

Microbiology: If the patient has a history of infection (either within the last year or more than one year ago) with a multi-drug resistant (MDR) organism select the type of organism. MDR is defined as resistance to at least one agent in three or more antimicrobial classes.¹¹⁵ If the history of infection is not listed below, it does not need to be reported.¹¹⁶

Burkholderia cenocepacia (genomovar III)

Burkholderia gladioli

¹⁰⁹ "Management of COPD exacerbations: a European Respiratory Society/American Thoracic Society guideline," *European Respiratory Journal* (2017): 1-16, DOI: 10.1183/13993003.00791-2016.

¹¹⁰ Maya M. Juarez, Andrew L. Chan, and Andrew G. Norris, et al., "Acute exacerbation of idiopathic pulmonary fibrosis – a review of current and novel pharmacotherapies," *Journal of Thoracic Disease* 7 no. 3 (2015):499-519, doi: 10.3978/j.issn.2072-1439.2015.01.17.

¹¹¹ P.A. Flume, P.J. Mogayzel Jr, and K.A. Robinson, et al., "Clinical Practice Guidelines for Pulmonary Therapies Committee. Cystic fibrosis pulmonary guidelines: treatment of pulmonary exacerbations." *American Journal of Respiratory and Critical Care Medicine* 180 no. 9 (2009):802-808. doi: 10.1164/rccm.200812-1845PP.

¹¹² Ibid.

¹¹³ Ryan Naum and Brittany Speed, "Hemoptysis in Pediatric Patients," *Cureus* 11 no. 3 (2019): e4305, doi: 10.7759/cureus.4305.

¹¹⁴ "Cardiac catheterisation measurements," Pulmonary Hypertension Association UK, accessed June 30, 2022, <https://www.phauk.org/tests-you-might-have/cardiac-catheterisation/cardiac-catheterisation-measurements/>.

¹¹⁵ A.-P. Magiorakos, A. Srinivasan, R.B. Carey, et al., "Multidrug-resistant, extensively drug-resistant and pandrug-resistant bacteria: an international expert proposal for interim standard definitions for acquired resistance," *Clinical Microbiology and Infection* 18 (2012): 268-281, doi: 10.1111/j.1469-0691.2011.03570.x.

¹¹⁶ Data definition is similar to current data definition on the Lung TCR for "Pan-Resistant Bacterial Lung Infection."

MDR or Pan-R gram negative bacteria**Mycobacterium abscessus**

Scedosporium/Pseudallescheria species complex/Lomentospora **Test Date:** Enter the date when this information was obtained.

NYHA Functional Classification: If the patient has pulmonary hypertension as a primary diagnosis, select the patient’s New York Heart Association (NYHA) classification. The NYHA classification classifies patients in one of four categories based on their limitations during physical activity; the limitations/symptoms are in regards to normal breathing and varying degrees in shortness of breath and/or angina pain.¹¹⁷

Class I - No symptoms and no limitation in ordinary physical activity, e.g. shortness of breath when walking, climbing stairs, etc.

Class II - Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III - Marked limitation in activity due to symptoms, even during less-than-ordinary activity, e.g. walking short distances (20–100 m). Comfortable only at rest.

Class IV - Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients.

Eval Date: Enter the date when this information was obtained.

Pericardial Effusion: If the patient is currently experiencing pericardial effusion as detected on echocardiogram, select **Yes**. If not select **No**.

Definition: Pericardial effusion refers to increased fluid within the pericardial sac which can cause circulatory compromise by compression of the heart; most often caused by inflammation, infection, malignancy, and uremia.¹¹⁸

Test Date: Enter the date when this information was obtained.

Prior Lung Surgery: If the patient had prior lung surgery select the laterality (left, right, or both) and type of surgery.¹¹⁹

Prior lung transplant**Pneumonectomy****Lung volume reduction surgery****Wedge resection****Lobectomy****Pleural procedures****Decortication****Pleurectomy****Pleurodesis**

¹¹⁷ New York Heart Association (NYHA) Classification, Specifications Manual for Joint Commission National Quality Measures (v2018A), accessed January 26, 2022, <https://manual.jointcommission.org/releases/TJC2018A/DataElem0439.html>

¹¹⁸ Daniel A. Willner, Amandeep Goyal, Yulia Grigorova, et al., “Pericardial Effusion,” *StatPearls* (2021), <https://www.ncbi.nlm.nih.gov/books/NBK431089/>.

¹¹⁹ Data definition is similar to current data definition on the Lung TCR for “Prior Lung Surgery (non-transplant).”

Chemical

Mechanical

Talc

Other, specify

Prior Cardiac Surgery: If the patient had prior cardiac surgery select the type of surgery.¹²⁰ Only non-percutaneous interventions should be reported.

Sternotomy – CABG (coronary artery bypass graft surgery)

Sternotomy – Congenital

Sternotomy – Maze

Sternotomy – Valve replacement

Other, specify

Pulmonary Vascular Resistance (PVR): Enter the pulmonary vascular resistance value obtained from a right heart catheterization in dynes/sec/cm⁵ OR wood units (mmHg/L/min).

Definition: Pulmonary vascular resistance is the resistance against blood flow from the pulmonary artery to the left atrium.¹²¹

Test Date: Enter the date when this information was obtained.

Requires Supplemental O₂: If the patient requires supplemental oxygen, indicate when supplemental oxygen is required and what type of oxygen supply system is used (face mask, high flow nasal cannula, nasal cannula, reservoir cannula, BiPAP, CPAP, continuous mechanical – hospitalized, continuous mechanical – not hospitalized, intermittent mechanical – hospitalized, or Intermittent mechanical – not hospitalized). A high flow nasal cannula is a device that allows for independent titration of L/min and FiO₂. Enter the amount needed in L/min (the value must fall between 0.25 and 100) or in percent (the value must fall between 22 and 100). For the purposes of calculating the patient's composite allocation score, a substituted value of 26.33 will be used for any values entered over 26.33.¹²² Use of average volume-assured pressure support (AVAPS) should be reported as **intermittent mechanical**.

At rest (not moving or exerting oneself)

With exercise

With sleep

Eval Date: Enter the date when this information was obtained.

Six minute walk distance: Enter the total exertional distance on a flat surface the candidate is able to walk in six minutes in feet. The distance walked is a measure of functional status. The normal range is between 0 and 3000, although a value outside of this range may be entered. Enter the **Test Date** when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the waiting list. If they are incomplete or expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.¹²³

¹²⁰ Ibid.

¹²¹ Jason Widrich and Mrin Shetty, "Physiology, Pulmonary Vascular Resistance," *StatPearls* (2021), <https://www.ncbi.nlm.nih.gov/books/NBK554380/>.

¹²² Proposed data definition is based on the current data definition on the Lung Candidate Record in OPTN Waiting List, with modifications to reflect proposed changes to data collection.

¹²³ Ibid.