OPTN

Public Comment Proposal

Update Data Collection for Lung Mortality Models

OPTN Lung Transplantation Committee

Prepared by: Kaitlin Swanner and Krissy Laurie
UNOS Policy and Community Relations Department

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OPTN

Update Data Collection for Lung Mortality Models

Affected Policies:	*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*
Data Collection Affected:	*Lung OPTN Waiting List*
Sponsoring Committee:	*Lung Transplantation*
Public Comment Period:	*August 3, 2022 – September 28, 2022*

Executive Summary

The current lung allocation score is based on estimates of a candidate's waiting list survival and post-transplant survival. A new lung composite allocation score approved by the OPTN Board of Directors in December 2021 accounts for waiting list survival and post-transplant survival as well as several other factors, like blood type and height. 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 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, but it would assign values for parts of the score for candidates on extracorporeal membrane oxygenation (ECMO) or high flow nasal cannula.

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 score 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.[2] These changes were implemented on September 30, 2021,[3] along with some additional refinements to lung data fields.[4,5] Second, the proposal to *Establish Continuous Distribution of Lungs*[6] changed how the waiting list survival and post-transplant outcomes scores factor into allocation. For the waiting list survival score, there was no change to the mortality model or inputs used to determine this score, but there were

[1] "A Guide to Calculating the Lung Allocation Score," OPTN, accessed July 7, 2022, https://optn.transplant.hrsa.gov/media/cn0jy5zy/a-guide-to-calculating-the-lung-allocation-score.pdf.
[2] "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/.
[3] Notice of Implemented Actions, OPTN, accessed June 7, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions/.
[4] "Refine Lung Data Fields," OPTN, accessed June 19, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/refine-lung-data-fields/
[5] 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.
[6] "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.

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 inputs to the score did not change, but the mortality model was updated to estimate five years of post-transplant survival rather than one-year post-transplant survival.

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. 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.

Overview of Proposal

The Committee proposes several changes to data collection for lung candidates in the OPTN Waiting List, including removing data collection on five clinical criteria; revising data collection for five other clinical criteria; and adding data collection on fourteen 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 means allowing 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 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.[7,8,9]
Post Bronchodilator Actual FEV_1	This variable is not used to calculate a candidate's waitlist survival or post-transplant outcomes.[10]
Pre Bronchodilator Percent Predicted FEV_1	This variable is not used to calculate a candidate's waitlist survival or post-transplant outcomes, and can be calculated from other data submitted.[11]
Post Bronchodilator Percent Predicted FEV_1	This variable is not used to calculate a candidate's waitlist survival or post-transplant outcomes, and can be calculated from other data submitted.[12]
Requires Supplemental O_2: How was the value obtained	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 O_2. 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.[13]

Data Revisions

The Committee proposes revising data collection on five clinical criteria that are currently collected 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.

[7] "Spirometry Reference Value Calculator," National Institute for Occupational Safety and Health, accessed June 23, 2022, https://www.cdc.gov/niosh/topics/spirometry/refcalculator.html.
[8] 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.
[9] 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
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] 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.

Table 2: Proposed Revisions

Clinical Criteria	Rationale
Lung Diagnosis Code – addition of *Combined Pulmonary Fibrosis and Emphysema (CPFE)*	Transplant programs have submitted exception requests for candidates with CPFE.[14] These candidates were registered under the diagnosis code of *Idiopathic Pulmonary Fibrosis (IPF),* which may not accurately reflect the severity of disease, according to clinical literature which suggests that these candidates have worse outcomes.[15,16,17,18] 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. [19,20]
Diabetes	The revisions would remove references to insulin "dependency" and instead request that programs indicate if the candidates are *treated* with insulin, since insulin use (rather than dependency) is associated with a higher risk of mortality.[21,22] 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.

[14] Per clinical narratives submitted to the OPTN for patients with exception requests between January 1, 2019, and December 31, 2020.
[15] 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.
[16] 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.
[17] 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.
[18] Tomoo Kishaba, Yousuke Shimaoka, and Hajime Fukuyama, et al., "A cohort story of mortality predictors and characteristics of patients with combined pulmonary fibrosis and emphysema," *BMJ Open* 2(2012): e000988, DOI: 10.1136/ bmjopen-2012-000988.
[19] Ibid.
[20] 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
[21] 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.
[22] Ibid.

Clinical Criteria	Rationale
Assisted Ventilation	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.[23] 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.
Requires Supplemental O_2	Current data collection on supplemental O_2 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, and the amount of supplemental oxygen delivered with exercise and with sleep, in addition to at rest. These changes are expected to improve data quality through consistency with how data is entered for various clinical circumstances.[24,25,26]

[23] 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
[24] Ibid.
[25] 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
[26] 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	The proposed revisions to this field include moving its placement under *Requires Supplemental O_2* since these data are often collected and entered at the same time by transplant coordinators. Additionally, the data definition would be modified to specify that this should be the *total exertional* distance *performed on a flat surface* (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 standard in the field for how to perform the six-minute walk and practice varies between programs. [27,28]

Requires Supplemental O_2

Current data collection on supplemental oxygen only allows transplant programs to enter the amount of supplemental oxygen 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 (FiO_2), 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.[29]

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	--

[27] 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
[28] 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.
[29] 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.

Device	Permitted Values	Computer System Actions
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 FiO_2 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 % FiO_2, and that patient's overall oxygen requirements might be lower than a patient using a lower flow rate in L/min but 100% FiO_2. 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 FiO_2 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 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 be choosing 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.

Data Additions

The Committee proposes adding data collection on fourteen clinical criteria, summarized in **Table 4**, for which there is clinical literature or a number of previous exception requests to indicate that the data may impact a candidate's waiting list survival or post-transplant outcomes. Many of these criteria are known or expected to be prognostic indicators, which means that the presence or absence of these characteristics impacts a patient's expected clinical outcomes. Three of these criteria would only apply to candidates with a diagnosis of pulmonary hypertension (indicated in the table as "PH diagnosis only").

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.[30,31,32,33]
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."[34] Transplant programs frequently collect and track these data for PH patients and research supports these data being a prognostic indicator.[35,36]
Pericardial effusion (PH diagnosis only)	The presence or absence of pericardial effusion for PH patients is seen as a prognostic indicator.[37,38]
Recurrent pneumothoraces (RPTx)	After a review of Lung Review Board exceptions, RPTx was identified as a theme in that pneumothoraces resulted in hospitalizations and clinical interventions (e.g. inserting chest tube), and prevented the use of noninvasive ventilator support. [39] The Committee proposes this addition to monitor these data as a possible prognostic indicator.[40]
Bronchopleural fistula (BPF)	After a review of Lung Review Board exceptions, BPF was identified as a theme in that BPF resulted in hospitalizations and clinical interventions (e.g. inserting chest tube),[41] so the Committee proposes this addition to monitor these data as a possible prognostic indicator.[42]

[30] 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
[31] 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
[32] 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
[33] Benza et al. *The REVEAL Registry risk score calculator in patients newly diagnosed with pulmonary arterial hypertension.* Chest 2012; 141:354.
[34] "NT-proB-type Natriuretic Peptide," Cleveland Clinic, accessed June 12, 2022, https://my.clevelandclinic.org/health/diagnostics/16814-nt-prob-type-natriuretic-peptide-bnp.
[35] 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.
[36] 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.
[37] 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
[38] 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.
[39] Per clinical narratives submitted to the OPTN for patients with exception requests between January 1, 2019, and December 31, 2020.
[40] Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, July 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/1aolsea5/20210722_lung-umm-subcommittee-meeting-summary.pdf
[41] Per clinical narratives submitted to the OPTN for patients with exception requests between January 1, 2019, and December 31, 2020.
[42] Ibid.

Clinical Criteria	Rationale
Massive hemoptysis, number of times in the last year	Clinical literature indicates that patients with a history of hemoptysis have worse outcomes.[43,44,45,46,47,48]
Exacerbations, number of times in the last year	After a review of Lung Review Board exceptions, exacerbations were identified as a theme in that patients with exacerbations required increased inpatient and outpatient clinical intervention. Exacerbations is also noted in clinical literature as a prognostic indicator,[49,50,51] and Committee members reported that in their experience, the occurrence of exacerbations tends to signal an inflection point of increased waitlist mortality.[52] The Committee proposes distinct data definitions for exacerbations for three diagnosis: chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), and cystic fibrosis (CF).[53,54,55,56]
Prior Lung Surgery	If the candidate had a procedure that entered the chest cavity, that can lead to scarring, which may make lung transplant more difficult and potentially impact post-transplant outcomes.[57,58,59]

[43] Ibid.
[44] 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.
[45] Clark et al. *Massive Hemoptysis in Cystic.* Chest 2005;128:729–38.
[46] Flight et al. *Outcomes Following Bronchial Artery Embolisation for Haemoptysis in Cystic Fibrosis.* Cardiovasc Intervent Radiol 2017;40(8):1164–8.
[47] 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.
[48] 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
[49] Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, July 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/1aolsea5/20210722_lung-umm-subcommittee-meeting-summary.pdf
[50] 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
[51] 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.
[52] Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary, July 22, 2021, OPTN, accessed March 22, 2022, https://optn.transplant.hrsa.gov/media/1aolsea5/20210722_lung-umm-subcommittee-meeting-summary.pdf
[53] 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.
[54] "Management of COPD exacerbations: a European Respiratory Society/American Thoracic Society guideline," *European Respiratory Journal* (2017): 1-16, DOI: 10.1183/13993003.00791-2016.
[55] 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.
[56] 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.
[57] 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.
[58] 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
[59] 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

Clinical Criteria	Rationale
Pleurodesis	Pleurodesis is a type of lung surgery. The Committee proposes collecting this information in addition to "Prior Lung Surgery" to gather more information on the type of pleurodesis performed.[60,61] For example, the performance of a chemical pleurodesis and prolonged cardiopulmonary bypass were significantly associated with mortality in lung transplant candidates.[62]
Prior Cardiac Surgery	If the candidate had a procedure that entered the chest cavity, that can lead to scarring, which may make lung transplant more difficult and potentially impact post-transplant outcomes. [63,64,65]
Microbiology	Literature indicates that *Burkholderia cenocepacia* and *Mycobacterium abscessus* infections impact post-transplant morbidity.[66,67,68] Case studies report that *Burkholderia gladioli*[69] and *Scedosporium/Pseudallescheria* species complex[70] may also be associated with post-transplant morbidity. The Committee proposes also including data collection in OPTN Waiting List that mirrors the *Pan-Resistant Bacterial Lung Infection* data collection on the Lung Transplant Candidate Registration (TCR).

[60] 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
[61] 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
[62] Shigemura et al. Lung transplantation in patients with prior cardiothoracic surgical procedures. Am J Transplant. 2012 May;12(5):1249-55.
[63] 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.
[64] 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
[65] 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
[66] Huang HC, Weigt SS, Derhovanessian A, Palchevskiy V, Ardehali A, Saggar 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
[67] 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
[68] 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.
[69] 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.
[70] Florent Morio, Delphine Horeau-Langlard, and Francoise 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.[71,72,73]
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.[74]
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.[75]

Two of these clinical criteria – prior lung surgery and prior cardiac surgery – are currently collected on the Lung TCR and Transplant Recipient Registration data collection instruments; still, the Committee proposes adding them to the OPTN Waiting List with revisions to capture additional information that could impact a candidate's expected mortality. The Committee intends to collect all data that could be factored into the lung CAS in the OPTN Waiting List. This way, it would be easier for the OPTN to implement changes to the lung CAS in the future if these clinical criteria are incorporated into the score. Changes to the TCR and TRR to align data collection across OPTN systems were out of scope for this proposal.

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

[71] 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
[72] 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
[73] 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/
[74] 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.
[75] Ibid.

those with IPF.[76,77,78,79] 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.[80] 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 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,[81] but in the absence of this option, the OPTN Thoracic Organ Transplantation Committee offered guidance to transplant programs 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 FiO_2 of 100%.[82] Currently, the system converts the 100% FiO_2 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

[76] 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.
[77] 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.
[78] 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.
[79] Tomoo Kishaba, Yousuke Shimaoka, and Hajime Fukuyama, et al., "A cohort story of mortality predictors and characteristics of patients with combined pulmonary fibrosis and emphysema," *BMJ Open* 2(2012): e000988, DOI: 10.1136/ bmjopen-2012-000988.
[80] "Proposal to Revise the Lung Allocation Score (LAS) System," OPTN, 2012.
[81] "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.
[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/.

candidate's oxygen needs while still giving candidates the appropriate allocation score based on their urgency status.

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 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]

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."[86] The OPTN Final Rule states that the OPTN "shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[87] 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."[88] 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…"[89] This proposal would update the information collected on lung transplant candidates to improve the models used to assign scores to candidates in lung allocation.

[83] "Principles for Data Collection," OPTN, accessed June 12, 2022, https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[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] 42 USC §274(b)(2)(B)
[87] 42 CFR §121.4(a)(1)
[88] 42 C.F.R §121.11(a)(1)(i)-(ii)
[89] 42 CFR § 121.11(b)(2)

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."[90] This proposal:

- **Is based on sound medical judgment**[91] 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**[92] **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**[93]**:** 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**[94] **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.**[95]

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[96] and it is specific to an organ type, in this case lung.[97]

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 organs[98]
- Promotes the efficient management of organ placement[99]

[90] 42 CFR §121.8(a)
[91] 42 CFR §121.8(a)(1)
[92] 42 CFR §121.8(a)(2)
[93] Id.
[94] Id.
[95] 42 CFR §121.8(a)(8)
[96] 42 CFR §121.8(a)(3)
[97] 42 CFR §121.8(a)(4)
[98] 42 CFR §121.8(a)(5)
[99] Id.

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.[100] 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 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.

Implementation Considerations

Member and OPTN Operations

Transplant hospitals and the OPTN would need to take actions to implement this proposal, but the proposal is not anticipated to affect the operations of organ procurement organizations (OPOs) or histocompatibility laboratories.

Operations affecting Transplant Hospitals

Transplant hospitals will need to become familiar with the changes to data collection for lung transplant candidates. The data collection that the Committee proposes revising are required data fields as most of those fields are used to calculate the candidate's score for lung allocation. Transplant hospitals are not required to complete the new data collection proposed by the Committee, but the Committee recommends that transplant hospitals enter as much of this data for their candidates as possible in order to improve the mortality models used in lung allocation.

Operations affecting the OPTN

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,[101] and will include updates on data collection in OPTN Waiting List regarding ECMO status and type of 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 venoarterial (VA) or venovenous (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.

[100] 42 CFR § 121.8(d)
[101] "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.

Potential Impact on Select Patient Populations

This proposal would collect additional data on lung candidates, including some data specific to patients with pulmonary hypertension (PH). Other data are expected to capture additional clinical information related to survival for candidates with cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), combined pulmonary fibrosis and emphysema (CPFE), and interstitial lung disease (ILD), including idiopathic pulmonary fibrosis (IPF). The Committee expects to use these data to evaluate whether to update the score calculations used for lung allocation. This will help to ensure that patients with these diagnoses receive the appropriate priority on the waiting list for transplant.

Additionally, while this proposal largely does not change how the lung composite allocation score is calculated, it would assign values for parts of the score for candidates on ECMO or high flow nasal cannula. Patients reported as being on ECMO under "assisted ventilation" would be assigned the maximum score for the supplemental oxygen variable in the allocation score. Patients receiving supplemental oxygen via high flow nasal cannula who have both L/min and % values reported will receive the most beneficial score for this variable depending on whether the L/min value or converted % value is higher. The Committee proposes these value assignments due to their preference not to disadvantage a candidate relative to the current allocation system, due to the absence of detailed data on the impact of ECMO status and oxygen requirements on expected waitlist survival and post-transplant outcomes.

Projected Fiscal Impact

The proposal is expected to have a fiscal impact on transplant hospitals and the OPTN, but no expected fiscal impact on OPOs or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

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.

Projected Impact on the OPTN

The OPTN supported Committee meetings as well as drafting, review, and revisions of proposed data collection and policy changes. This proposal would require implementation of data collection changes in OPTN Waiting List, additional monitoring, and communication to members.

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."[102] 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.

Considerations for Community

The Committee requests feedback on the following questions:

- Are the proposed data changes and data definitions clear?
- What clinical parameters, if any, would you add to the diagnosis-specific data definitions of exacerbations?
- Is it clear how data should be submitted related to assisted ventilation and supplemental oxygen, and how values entered in these fields or other assigned values will be incorporated into the lung CAS?
- Are there any other clinical criteria that should be added to better estimate a candidate's waiting list survival or post-transplant outcomes?
- Should any of the proposed clinical criteria not be included in the OPTN Waiting List?
- Is there a need to retain any of the clinical criteria proposed for removal?

[102] 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. The […] signifies language in the current Policy that is not presented here for the purposes of brevity and will not be affected by the proposal.

10.1.F Lung Disease Diagnosis Groups

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

Group D

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

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Combined pulmonary fibrosis and emphysema (CPFE)
- Constrictive bronchiolitis
- COVID-19: acute respiratory distress syndrome
- COVID-19: pulmonary fibrosis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis
- Idiopathic interstitial pneumonia, with at least one of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - Respiratory bronchiolitis-associated interstitial lung disease
    - Idiopathic pulmonary hemosiderosis
    - Lung retransplant or graft failure: acute rejection
    - Lung retransplant or graft failure: non-specific
    - Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
    - Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
    - Lung retransplant or graft failure: obstructive

- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with PA mean pressure greater than 30 mm Hg
- Scleroderma – restrictive
- Silicosis
- Sjogren's syndrome
- Surfactant protein B deficiency
- Surfactant protein C deficiency
- Teratoma
- Wegener's granuloma – restrictive

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* 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:
[…]		
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Greater than 26.33 L/min	26.33L/min needed at rest

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
Assisted ventilation	ECMO	26.33L/min needed at rest for the "amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)" covariate
[…]		

[…]

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

[…]

If values for certain covariates are missing, expired, or ~~below~~outside the threshold as defined by *Table ~~10-~~ 4*21-7, then the composite allocation score calculation will substitute ~~normal or least beneficial~~ values to calculate the candidate's post-transplant outcomes score. *Table 21-7: Values Substituted for Missing or Expired Actual Values in Calculating Post-Transplant Outcomes Score* lists the ~~normal and least beneficial~~ values that will be substituted.

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.

Lung OPTN Waiting List

Data Removals

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

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	**Current selection options:** BiPAP CPAP Continuous mechanical – hospitalized Continuous mechanical – not hospitalized ECMO Intermittent mechanical No assisted ventilation needed	**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
Requires Supplemental O_2	**Current selection options with the ability to enter one with one evaluation date:** At rest At night With exercise only **Current units:** Max of 26.33 L/min	**Revise selection options to allow for multiple entries and add evaluation dates for all three:** At rest With exercise With sleep **Proposed units:** Max of 100 L/min **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)
Six Minute Walk Distance	Integer value (no change)	Moved field to be below *Requires Supplemental O_2* for better flow of data entry

Data Additions

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
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
Recurrent pneumothoraces (RPTx)	Yes, No	Add to the OPTN Waiting List
Bronchopleural fistula (BPF)	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
Prior Lung Surgery	**Selection options:** None **Left, Right** Prior lung transplant Pneumonectomy Lung Volume Reduction Surgery Open Wedge Resection Lobectomy Decortication Video-assisted thoracic surgery (VATS) Other, specify (with free text)	Add to the OPTN Waiting List with option to select more than one
Pleurodesis	**Selection options:** None **Left, Right** Chemical Mechanical Talc	Add to the OPTN Waiting List with option to select more than one

Clinical Criteria	Values	Recommended Changes & Comments
Prior Cardiac Surgery	**Selection options:** None CABG Sternotomy Congenital Maze Valve replacement Other, specify (with free text)	Add to the OPTN Waiting List with option to select more than one
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 ≤ 1 year *Scedosporium/Pseudallescheria* species complex > 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/cm5 or Wood units (mmHg/L/min)	Add to the OPTN Waiting List as part of the most recent heart catheterization data section

Lung OPTN Waiting List Serial Data Collection

Clinical Criteria *Six-month prior to listing data*	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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Proposed Data Definitions

Lung OPTN Waiting List

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.[103]

Bronchopleural fistula (BPF): If the patient is currently experiencing a bronchopleural fistula (BPF) select **Yes**. If not, select **No**.

Definition: Bronchopleural fistula is a sinus tract between the main stem, lobar, or segmental bronchus and the pleural space due to pneumothoraces, infection, overzealous mechanical ventilation, or bullous disease or blebs.[104]

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.[105]

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. 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.[106]

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.

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.[107]

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[103] Rasmus Rørth, Pardeep S. Juhund, 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.

[104] Irim Salik, Rishik Vashisht, and Apolonia E. Abramowitz, "Bronchopleural fistula," *StatPearls* (2022) https://www.ncbi.nlm.nih.gov/books/NBK534765/.

[105] 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.

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

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

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.[108]

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.[109]

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.[110] 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.[111]

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.[112]

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 organism select the type of organism. If the history of infection is not listed below, it does not need to be reported.[113]

Burkholderia cenocepacia (genomovar III)

Burkholderia gladioli

MDR or Pan-R gram negative bacteria

Mycobacterium abscessus

Scedosporium/Pseudallescheria species complex

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.[114]

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

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[108] 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.
[109] 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.
[110] Ibid.
[111] Ryan Naum and Brittany Speed, "Hemoptysis in Pediatric Patients," *Cureus* 11 no. 3 (2019): e4305, doi: 10.7759/cureus.4305.
[112] "Cardiac catheterisation measurements," Pulmonary Hypertension Association UK, accessed June 30, 2022, https://www.phauk.org/tests-you-might-have/cardiac-catheterisation/cardiac-catheterisation-measurements/.
[113] Data definition is similar to current data definition on the Lung TCR for "Pan-Resistant Bacterial Lung Infection."
[114] 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

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.

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.[115]

Pleurodesis: If the patient had pleurodesis, select the laterality (left, right, or both) and type of procedure (chemical, mechanical, or talc).

Definition: Pleurodesis is the creation of a fibrous adhesion between the visceral and parietal layers of the pleura, thus obliterating the pleural cavity.[116]

Prior Lung Surgery: If the patient had prior lung surgery select the laterality (left, right, or both) and type of surgery.[117]

Prior lung transplant

Pneumonectomy

Lung volume reduction surgery

Open Wedge resection

Lobectomy

Decortication

VATS (Video-assisted thoracic surgery)

Other, specify

Prior Cardiac Surgery: If the patient had prior cardiac surgery select the type of surgery.[118]

CABG (coronary artery bypass graft surgery)

Sternotomy – Congenital

Sternotomy – Maze

Sternotomy – Valve replacement

Other, specify

[115] Daniel A. Willner, Amandeep Goyal, Yulia Grigorova, et al., "Pericardial Effusion," *StatPearls* (2021), https://www.ncbi.nlm.nih.gov/books/NBK431089/.
[116] Farlex Partner Medical Dictionary. S.v. "pleurodesis." Retrieved June 30 2022 from https://medical-dictionary.thefreedictionary.com/pleurodesis.
[117] Data definition is similar to current data definition on the Lung TCR for "Prior Lung Surgery (non-transplant)."
[118] Ibid.

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.[119]

Recurrent pneumothoraces (RPTx): If the patient is experiencing pneumothorax that recurs on the same side 30 days or more after the initial resolution, select **Yes**. If not, select **No**.

> **Definition:** Pneumothorax refers to the accumulation of air or gas in the pleural cavity, resulting in a collapse of the lung on the affected side.[120]

Requires Supplemental O_2: If the patient requires supplemental oxygen, indicate when supplementation 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 FiO_2. 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.[121]

> **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.[122]

[119] Jason Widrich and Mrin Shetty, "Physiology, Pulmonary Vascular Resistance," *StatPearls* (2021), https://www.ncbi.nlm.nih.gov/books/NBK554380/.
[120] Catherine L. McKnight and Bracken Burns, "Pneumothorax," *StatPearls* (2022), https://www.ncbi.nlm.nih.gov/books/NBK441885/.
[121] 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.
[122] Ibid.