OPTN

Notice of OPTN Policy and Data Collection Changes

Update Data Collection for Lung Mortality Models

Sponsoring Committee:	**OPTN Lung Transplantation Committee**
Policies Affected:	***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**
	Lung Data System for Organ Procurement and Transplantation Network
Public Comment:	**August 3, 2022 – September 28, 2022**
Board Approved:	**December 5, 2022**
Effective Date:	**Pending implementation and notice to members**

Purpose of Policy and Data Collection Changes

The OPTN will update data collection in OPTN Waiting List and the Data System for OPTN on disease severity of lung candidates by removing, revising, and adding data collection. These data collection updates will not change the variables, coefficients, rating scales, or weights used to calculate the lung composite allocation score (CAS), but values will be assigned for parts of the score for candidates on extracorporeal membrane oxygenation (ECMO) or high flow nasal cannula. The purpose of the data collection changes is to inform future updates to the mortality models used for calculating the lung CAS.

Proposal History

The OPTN implemented several improvements[1,2] to the waiting list and post-transplant survival components of the score used for allocation while developing the new lung composite allocation score (CAS) for continuous distribution of lungs.[3] The changes outlined in this notice build upon those improvements by 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 are expected to impact a lung candidate's waiting list survival or post-transplant outcomes. The OPTN will also implement new data collection on these criteria.

[1] "Updated Cohort for Calculation of the Lung Allocation Score," OPTN, accessed November 30, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/updated-cohort-for-calculation-of-the-lung-allocation-score-las/.
[2] "Refine Lung Data Fields," OPTN, accessed November 30, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/refine-lung-data-fields/.
[3] "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.

Summary of Changes

The OPTN will implement 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 clinical criteria; and adding data collection on nine clinical criteria. The revisions will include updates to the lung Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR). The OPTN will also implement serial data collection for three clinical criteria, two of which are already currently collected by the OPTN. Serial data collection allows transplant programs to enter data for multiple dates.

The OPTN will implement three policy changes related to the modified data collection: one change to add a new diagnosis code, and two changes in substituted values used in the waiting list survival score calculation for supplemental oxygen data collection.

Implementation

Transplant hospitals will need to become familiar with the changes to data collection for lung transplant candidates. 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 Office of Management and Budget (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.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

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
- <u>Combined pulmonary fibrosis and emphysema (CPFE)</u>
- 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: 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
Assisted ventilation	ECMO, and not expired	26.33L/min needed at rest for the "amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)" covariate
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
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Greater than 26.33 L/min at rest, and not expired	26.33L/min needed at rest
Amount of supplemental oxygen required to maintain adequate oxygen saturation (88% or greater) (L/min)	Missing or expired	No supplemental oxygen needed at rest

If this covariate's value:	Is:	Then the waiting list survival calculation will use this substituted value:
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

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 Values ~~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

Affected Data Collection

Data Removals: Lung OPTN Waiting List

Clinical Criteria	Values	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	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
Assisted Ventilation	**Current selection options:** BiPAP CPAP Continuous mechanical – hospitalized Continuous mechanical – not hospitalized ECMO Intermittent mechanical	**Revise selection options to:** BiPAP CPAP Continuous mechanical – hospitalized Continuous mechanical – not hospitalized ECMO VA – mechanically ventilated VA – not mechanically ventilated VV – mechanically ventilated

Clinical Criteria	Values	Changes & Comments
	No assisted ventilation needed	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 Changes: Lung Data System for OPTN

Clinical Criteria	Values	Changes & Comments
Prior Lung Surgery	**Current selection options (TRR):** Pneuomoreduction Pneumothorax Surgery-Nodule	Remove from TRR; add to TCR with revised selection options (can select more than one)

Clinical Criteria	Values	Changes & Comments
	Pneumothorax Decortication Lobectomy Pneumonectomy Left Thoracotomy Right Thoracotomy Other, specify	**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	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	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

Clinical Criteria	Values	Changes & Comments
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

Serial Data Collection: Lung OPTN Waiting List

Clinical Criteria *Six-month prior to listing data*	Values	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.