OPTN Lung Transplantation Committee
Updating Mortality Models Subcommittee
Meeting Summary
July 22, 2021
Conference Call

Erika Lease, MD, Chair
Marie Budev, DO, Vice Chair

Introduction

The Lung Transplantation Committee's Updating Mortality Models Subcommittee met via Citrix GoTo teleconference on 07/22/2021 to discuss the following agenda items:

1. Lung Review Diagnoses Exception Themes
2. Discussion of Future Data Field Additions

The following is a summary of the Subcommittee's discussions.

1. Lung Review Diagnoses Exception Themes

The Chair further reviewed and presented overview of diagnoses exception requests for unique patients with idiopathic pulmonary fibrosis (IPF) and chronic obstructive pulmonary disease (COPD)/Emphysema from 2019-2020 which were presented during the May 2021 Subcommittee meeting and noted the following themes for consideration in future data collection:[1]

Symptom	Total
Recurrent pneumothorax/persistent bronchopleural fistula	9
Rapid progression	4
Frequency of exacerbations	4
Combined pulmonary fibrosis and emphysema (CPFE)	2

2. Discussion of Future Data Field Additions

The Subcommittee discussed the following possible opportunities for future additional data collection and utilizing data already being collected to look at any possible impacts on waitlist mortality and/or post-transplant survival once continuous distribution is implemented:

- Delta changes
- Patient history
- Pulmonary hypertension (PH)
- Possible poor prognostic indicators

Summary of discussion:

[1] "OPTN Lung Transplantation Updating Mortality Models Subcommittee Meeting Summary (May 27, 2021),"OPTN, accessed August 17, https://optn.transplant.hrsa.gov/media/4706/20210527_lung-umm-subcommittee-meeting-summary.pdf

A member mentioned that a complete list of every meaningful data point would be difficult to achieve, but that the categories suggested would be a good starting place. The member also noted that there are some instances where a patient seems clinically urgent and vice versa and their current lung allocation score (LAS) does not seem to reflect the patient's status. It was stated that the LAS seems to work most of the time, but there are these instances with certain diagnoses and circumstances where the suggested additional data collection may better capture and reflect a more appropriate score.

The Chair explained that some of the suggested data points are currently collected, but are not included in the calculation, so they would not be an additional data collection (such as delta change). They continued to explain that some of the other categories (such as hemoptysis) may be more difficult to make into a data point and would require more discussion on how to appropriately define and collect the data. The Chair noted that delta change for certain criteria may be pertinent for IPF patients as described in the reviewed exception requests. A member asked for clarification on whether or not prior thoracic surgery was already collected and it was clarified that it is prior cardiac surgery. The member also stated that there is collection for PAN-resistance, but there are more resistances that if captured would be helpful and the Chair agreed, but would have to define what is considered multi-drug resistance.

A member asked for clarification on hemoptysis in cystic fibrosis (CF) patients and noted that typically when a patient experiences hemoptysis the thought is to transplant as soon as possible, but if it resolves there is still a concern that it will reoccur. The Chair stated that they had requested exceptions for patients that have massive hemoptysis, but have not been intubated, especially if they have had more than one episode of hemoptysis. They also noted that the data supports that patients with a history of hemoptysis have worse outcomes, but can we collect additional data that may not be included in the calculation of waitlist mortality right now, but could be included later while keeping in mind that the Subcommittee needs to be thoughtful about how hemoptysis would be defined and how the information would be collected to get the desired information. A member stated that it seems that if the hemoptysis is significant enough to attempt a bronchial artery embolization that could be something to look for, but the Chair mentioned that there are cases where the bleeding has stopped before the procedure is performed and that their CF group is hesitant to perform them due to the risk of hypercarbic respiratory failure. The Chair stated that there are some definitions of massive hemoptysis, but is unsure of how to appropriately capture recurrent small volume hemoptysis. A member suggested that the Subcommittee continues with trying to be patient centric and trusting colleagues with their interpretation of hemoptysis events and give the patients the benefit of higher scores or a granted exception. The Chair clarified that hemoptysis would continue to need an exception, but that the data could be collected for possible future inclusion in the waitlist calculation and offered to review the CF literature for definitions of massive, submassive, and recurrent hemoptysis.

The Chair asked for feedback on patients with recurrent pneumothorax/persistent bronchopleural fistula (BPF) and how that could be captured in a data point. A member suggested that a patient that has a chest tube that cannot be removed should be considered differently than a patient that has recurring need for a chest tube. They acknowledged that both scenarios are not good, but there is a greater urgency with patients that persistently have the chest tube. The Chair asked for possible timeframes on persistence (i.e. 10-14 days). A member noted that it may depend on where the patient is at in their transplant window and another member initially felt that somewhere between a two to four week timeframe may be appropriate. A member thought that initially using a four week period would give an idea since everyone would agree that would be considered persistent and could adjust based on the data that comes in.

The Chair suggested that for frequency of exacerbations, especially in CF patients, data collection could include number of days on treatment antibiotics over a certain period of time which should be easy to capture. They asked for feedback on what could be collected for frequency of exacerbations in COPD patients and suggested considering days on "acute need for steroids" versus chronic steroids, days on antibiotics and acute steroids, or simply number of exacerbations which would need to be defined. They mentioned that data collection should be able to show an inflection point of increased waitlist mortality. A member asked if the transplant programs would define what an exacerbation is and provide the number of occurrences versus specific treatment interventions and the Chair stated those are possible options. Another member stated that they had more trust in a CF center to appropriately define what an exacerbation is, but not all centers. The Chair mentioned that there is literature on CF patients showing an increase in waitlist mortality when in the hospital for 29-42 days over a 12-month period.[2] Members supported collecting these data to review and the Chair offered to share the literature for Subcommittee review.

The Chair noted that prior lung surgery should also be captured and asked for feedback on what types of procedures information should be collected on. A member stated that capturing all types of lung surgery since their experience is that lung surgeons want to know if any prior lung surgery occurred. The Chair suggested it could be a yes or no question that asks for more detailed information if the patient has had a prior lung surgery and another member supported including all types of procedures if possible.

The Chair suggested considering the addition of factors of disease severity for pulmonary hypertension (PH) patients and noted that there has been an improvement since the 2015 additions of delta change of creatinine and bilirubin, but the field has since evolved. A member agreed and asked if we are capturing the types of medicines that are being administered. The Chair clarified that treatments specific to PH are not currently being captured and the member noted that may be helpful information. The Chair also noted that some of the information may be captured post-transplant, but we would need to incorporate that information pre-transplant.

The Chair asked for clarification on how much support would be needed in order to add these options for data collection and it was clarified that information supporting the data as mortality markers should be included in decisions for what to add.

Next Steps:

The Subcommittee will review the possible options that have been suggested and begin to expand on how these data should be defined and collected with supporting literature to discuss at the next Subcommittee meeting.

Upcoming Meeting

- September 23, 2021

[2] Carli J. Lehr, Melissa Skeans, Elliott Dasenbrook, Aliza Fink, Gabriela Fernandez, Albert Faro, and Maryam Valapour, "Effect of Including Important Clinical Variables on Accuracy of the Lung Allocation Score for Cystic Fibrosis and Chronic Obstructive Pulmonary Disease," *American Journal of Respiratory and Critical Care Medicine* 200(8) (October 2019): 1013-1021, https://pubmed.ncbi.nlm.nih.gov/31199166/

Attendance

- **Subcommittee Members**
  - Erika Lease, Chair
  - Dennis Lyu
  - John Reynolds
  - Staci Carter
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
  - Marilyn Levi
- **SRTR Staff**
  - Katie Audette
  - Melissa Skeans
  - Andrew Wey
  - David Schladt
- **UNOS Staff**
  - Janis Rosenberg
  - Leah Slife
  - Sara Rose Wells
  - Krissy Laurie
  - Tatenda Mupfudze
  - Susan Tlusty
  - Holly Sobczak
  - Elizabeth Miller