

**OPTN Lung Transplantation Committee
Updating Mortality Models Subcommittee
Meeting Summary
December 2, 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 12/2/2021 to discuss the following agenda items:

1. Timeline Updates
2. Future Data Field Additions Recap and Continuation

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

1. Timeline Updates

The Subcommittee was given an update on the new timeline for this project would go out for public comment in summer of 2022 to be considered at the December 2022 Board of Directors meeting.

2. Future Data Field Additions Recap and Continuation

The Chair gave a recap of all of the variables previously discussed by the Subcommittee as a review and to offer the chance to ask questions if needed.

The Subcommittee discussed the following possible opportunities for future additional data collection:

Summary of discussion:

Delta Change Variables

The Chair noted that capturing delta changes for certain variables has come up throughout discussions and would like to continue the discussion specifically on six minute walk (6MW), O₂ requirement, forced expiratory volume (FEV₁), and forced vital capacity (FVC).

A member thought that it would be beneficial to capture all of these as they would be helpful to understand disease progression since a patient may manifest progression in one but not the others. The member also asked about tracking hypercarbia and the Chair clarified that partial pressure of carbon dioxide (PCO₂) is being tracked as a delta change currently, but was not clear on that timeframe. The Chair agreed that all of these are pertinent and noted that many of these are already collected so should not add a lot of burden to transplant programs.

The Chair asked for feedback on the specific timeframes that would be used for capturing these delta changes, for example, entering data pre-listing to show the change. A member felt that over the prior year would be helpful for disease progression, but would also like more frequent entries for the patients that are crashing. It was clarified that every six months is the current update schedule. The member asked if it would be problematic to have different time intervals for different candidates. The Chair mentioned that they liked the data point of six months prior to listing and noted that while the required

update schedule is every six months while listed, most programs are updating more frequently to reflect the patient's current status. The Chair asked for clarification on whether or not the delta would update with every set of new numbers that are entered. It was clarified that UNOS staff would compile options for the deltas and provide that information to the Subcommittee for further discussion. The Vice Chair stated that the question here is how many delta change points are clinically valuable, such as is it more valuable to have many points at random intervals or a few points at set intervals.

The Subcommittee discussed ranking the proposed delta changes in order of importance. Members felt that 6MW should be prioritized since there is research supporting it as an indicator. The Chair stated that O₂ should be the least important since patients that are at a point of requiring a lot of oxygen regardless of whether or not that happened quickly would have high waitlist mortality and the Vice Chair agreed with that reasoning. The Chair noted it is more difficult to rank FVC and FEV₁ and a member stated they are more disease specific. The Vice Chair explained that since there are more idiopathic pulmonary fibrosis (IPF) patients, it may be beneficial to rank FVC before FEV₁. The Subcommittee supported prioritizing (if necessary) the variables as: 6MW, FVC, FEV₁, and O₂.

The Subcommittee further discussed how a prior to listing data point would be incorporated for delta changes and how that would be different than what it currently entered. The Vice Chair mentioned that it may just need to be wording that is added to explain that this is pre-listing information and leave the timeframe more open ended since that may be variable across patients. The Chair agreed that it makes sense to not have as many time restrictions for the data entered prior to listing. The Subcommittee was asked if prior listing data should also be incorporated for PCO₂. The Vice Chair thought it was an interesting point and asked if pre-listing data was ever looked at by the OPTN Lung Committee previously. The Chair did not recall, but members felt that it should be looked at and considered as an addition.

Next Steps:

Provide information on how the current delta changes (PCO₂, creatinine, and bilirubin) being collected and incorporated to use as a frame of reference for any possible new delta changes added to data collection.

Prior Lung Surgery

The Subcommittee reviewed the types of prior lung surgeries that they may want to capture and the granularity needed for these data. The Chair asked if specifying laterality of the procedure would be needed and the Vice Chair was not sure if that was important. Members noted that it may be relevant in single lung transplants, but that there are only a few of those being performed. A member also mentioned it may be helpful in the instance of bilateral pleurodesis.

The Subcommittee also discussed the form that would be appropriate to capture the information and that it would make the most sense to keep it with prior cardiac surgery on the transplant candidate registration form (TCR).

Members felt that not every type of prior lung procedure would need to be listed, but there should be some granularity, especially in the case of pleurodesis. A member suggested including lung volume reduction surgery, wedge resection, lobectomy, and decortication while also having a separate category for pleurodesis with the ability to specify the type. The Subcommittee supported this level of granularity. The Subcommittee was asked for feedback on whether or not a program should be able to select more than one. The Chair stated that the more times a patient has procedures in the chest cavity there would be more complicating factors when trying to perform a transplant. The Vice Chair asked if they should be captured all at once or if it is more helpful to have them as separate episodes and a

member felt that the information needed would not be improved by separate entries and supported capturing it all at once. The Subcommittee also felt that knowing the date of the procedure would not be helpful, just knowing the history of procedure would be needed. It was also noted that outside of pluerodesis, it is highly unlikely that these procedures would occur post-listing.

The Subcommittee supported the following to collect data on prior lung surgery:

- Prior Lung Surgery (Y/N):
 - If yes, specify:
 - Prior lung transplant
 - Pneumonectomy
 - Lung Volume Reduction Surgery
 - Wedge Resection
 - Lobectomy
 - Decortication
- Pleurodesis (Y/N):
 - If yes, specify:
 - Chemical
 - Mechanical

Prior Cardiac Surgery

The Subcommittee reviewed the types of prior cardiac surgeries that are currently collected and discussed revision and granularity needed for these data. Currently, the TCR collects prior cardiac surgery as a yes or no and then specifies either coronary artery bypass graft surgery (CABG), valve replacement/repair, congenital, left ventricular remodeling, or other. The Chair stated that CABG and valve replacement performed via sternotomy should be captured. A member suggested having an option for sternotomy and adding granularity there for maze procedures and valve replacement instead of listing that and members agreed. A member added from a pediatric standpoint, the number of sternotomies is what is considered over the exact type of procedure. The Chair noted that it was unclear what was meant by the current option of “left ventricular remodeling”. Other members were also not sure what it meant and supported removing it. A member asked if transcatheter aortic valve replacements (TAVR) would be included as part of valve replacement and the Vice Chair stated that they were not sure if there was anything that supported mortality factors those types of valve replacements. The Chair agreed that TAVRs should be left out and only collect valve replacements via sternotomy.

The Subcommittee supported the following to collect data on prior cardiac surgery:

- Prior Cardiac Surgery (Y/N):
 - If yes, specify:
 - CABG
 - Sternotomy
 - Congenital
 - Maze
 - Valve replacement
 - Other, specify

Microhistory/Multi-drug Resistant Organisms

The Subcommittee discussed data fields to include specific microhistory/multi-drug resistant (MDR) organisms since they may preclude transplant and transfer additional risk. A member suggested adding fields to capture *Burkholderia cenocepacia* and *Mycobacterium abscessus* since the literature supports

those types having impacts on post-transplant morbidity. Currently there is only a field that captures PAN-resistant (PAN-R) bacterial lung infection and it was noted that multi-drug resistance (MDR) is hard to define with the current treatments available. A member supported continuing to collect PAN-R since it is clinically relevant, but while the Chair agreed they clarified that it is difficult to collect good data on it since there have been many instances where the patient is reported to have PAN-R but it turns out they are not with the antibiotics now available. A member explained that sometimes programs look at microhistory as a risk and factor that into a patient's candidacy for transplant and that should be considered. A member agreed that it does add complexity to a patient's case. The Subcommittee supported leaving the current field while gathering information for clarity as well as adding fields for *Burkholderia cenocepacia* and *Mycobacterium abscessus*.

Next Steps:

Researching how the Cystic Fibrosis Foundation Registry defines MDR and PAN-R as well as consulting with the OPTN Disease Transmission Advisory Committee to possibly help define these to aid in data collection.

Outstanding Questions

The Subcommittee discussed the possibility of capturing the details of the types of surgeries with new procedure types becoming available. A member also noted that mini-thoracotomies are becoming more common and another member acknowledged that it may not be meaningful outside of interest on what is being performed. The Vice Chair clarified that since this would be more of an interest question it is something that we should put as lower priority. The Chair asked how thoracotomy would be differentiated from a mini-thoracotomy and the Vice Chair stated it would probably have to be in the surgeon's dictation as a mini-thoracotomy.

The Chair wanted to discuss the transplant recipient registration form (TRR) since there is a section for prior lung surgeries there, but felt it did not make sense to gather that information post-transplant. They also noted that it asks the same questions from the TCR for prior cardiac surgery which seems redundant. The Chair suggested removing the prior lung and cardiac surgeries from the TRR and only collect that information prior to transplant which is more useful to programs. The Subcommittee discussed that these forms have not been changed in a long time and it would be beneficial to look at them as a whole to clean them up as needed.

Next Steps:

Compile all of the Subcommittee's decisions for the revised and new data fields and put together mockups for the Subcommittee's review at the next meeting.

Upcoming Meeting

- January 6, 2022

Attendance

- **Subcommittee Members**
 - Erika Lease, Chair
 - Marie Budev, Vice Chair
 - Dennis Lyu
 - John Reynolds
 - Marc Schechter
 - Whitney Brown
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
 - David Schladt
- **UNOS Staff**
 - Leah Slife
 - Sara Rose Wells
 - Krissy Laurie
 - Tatenda Mupfudze
 - Susan Tlusty
 - Holly Sobczak
 - Elizabeth Miller