

**OPTN Lung Transplantation Committee
Updating Mortality Models Subcommittee
Meeting Summary
September 23, 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 09/23/2021 to discuss the following agenda items:

1. Future Data Field Additions

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

1. Future Data Field Additions

The Subcommittee discussed the following possible opportunities for future additional data collection and supported the following definitions and data collections for the following:

- Patient history
 - **Hemoptysis**
 - Definition: Massive 240>mL for adults and 8cc/kg in pediatrics
 - Data Collected: Yes or No and if yes, the number of times in the last year
 - Collected on all applicable patients, just cystic fibrosis (CF) patients
 - **World Health Organization (WHO) Functional Classification (Pulmonary hypertension (PH))**
 - Definition: Scale of Class I-V as defined by the WHO Functional Assessment for Pulmonary Hypertension¹
 - Data Collected: Scale of Class I-IV
 - This would be collected for primary diagnosis of PH only and need to be updated every six months
 - **BNP or proBNP**
 - Definition: Lab – pg/mL
 - Data Collection: BNP <50 proBNP <300
BNP 50-180 or proBNP 300-1500
BNP >180 or proBNP >1500

¹ WHO Functional Assessment for Pulmonary Hypertension, Table 2, Cleveland Clinic, accessed October 19, 2021, <https://www.clevelandclinicmeded.com/medicalpubs/pharmacy/marapr2002/table2.htm>

- The data collected would be the absolute value and the categorizations are based on the REVEAL risk factor score²
- **Pericardial effusion**
 - Definition: Data that is collected on echo
 - Data Collection: Yes or No
- **Mean Right Atrium Pressure (mRAP) >20mmHg within one year**
 - Definition: Data that is collected on right heart catheterization (RHC)
 - Data Collection: Actual value on RHC
- **Pulmonary Vascular Resistance (PVR) >32 wood unit (or >2560 dynes-sec/cm⁵)**
 - Definition: Data that is collected on RHC
 - Data Collection: Actual value on RHC
- **Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)**
 - Definition: Data that is collected on pulmonary function tests (PFTs)
 - Data Collection: >/+ 80% predicted
33-29% predicted
</= 32% predicted
- **Recurrent pneumothoraces (RPTx)**
 - Definition: Recurrence of pneumothorax is when it occurs on the same side 30 days or more after initial resolution
 - Data Collection: Yes or No (all incidents for the patient would be recorded without a time limit)
- **Bronchopleural fistula (BPF)**
 - Definition: 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
 - Acute
 - Subacute
 - Chronic
 - Data Collection: Yes or No, if BPF is present in the preceding 12 months to transplant listing with drop downs
- **Frequency of exacerbations**
 - Definition: Hospitalization or intravenous (IV) antibiotics
 - Data Collection: number of days of exacerbation/IV antibiotics/days in the hospital
- **Socioeconomic position (SEP)**
 - SRTR staff noted that some of the largest predictors are included in SEP, such as access to food, air quality, income, and insurance since they are hugely predictive of survival
 - Suggested collecting zip code or census zones

² Raymond L. Benza, Mardi Gomberg-Maitland, C. Greg Elliott, Harrison W. Farber, Aimee J. Foreman, Adaani E. Frost, Michael D. McGoon, David J. Pasta, Mona Selej, Charles D. Burger, and Robert P. Frantz, "Predicting Survival in Patients With Pulmonary Arterial Hypertension: The REVEAL Risk Score Calculator 2.0 and Comparison With ESC/ERS-Based Risk Assessment Strategies," CHEST, 156,2 (2019): 323-337, <https://www.sciencedirect.com/science/article/pii/S0012369219301527#!>

Summary of discussion:

Hemoptysis

The Vice Chair asked for feedback regarding if programs are concerned if a patient has any amount of hemoptysis, especially in CF patients and the Chair acknowledged that there is a concern when hemoptysis is present but there needs to be a clear definition for data collection. The Vice Chair suggested collecting binary yes or no data and the Chair felt that “massive” should be specified. Members also agreed that hemoptysis should exclude blood streaked sputum. A member stated that it is a bad sign to have any hemoptysis, and anything with pure blood is alarming. SRTR staff noted that thinking about each variable and the risk it provides may be beneficial. The Vice Chair added that specific information is not available for diagnoses outside of CF, but anecdotally it is a bad sign. HRSA staff asked if there should be a time frame on when hemoptysis would be relevant and members felt it would be appropriate to capture the data from within the last year. A member explained that what would qualify as “massive” in an adult would be excessively massive for a pediatric patient and suggested using 8cc/kg in pediatrics.

WHO Functional Classification

The Chair explained that the WHO Functional Classification is specifically related to PH, but could discuss its applicability to other diagnoses groups since idiopathic pulmonary fibrosis (IPF) and interstitial lung disease (ILD) patients also get really sick. The Vice Chair noted that this is a well-used scale and is used to determine medications. The Chair suggested that this variable should be updated regularly and felt that six-month intervals would be appropriate. A member stated that either cardiologists or pulmonologists that use the WHO scale are using it for PH and would suggest limiting it to that diagnosis. The Subcommittee supported limiting this data collection to PH patients and having it updated every six months.

BNP or proBNP

The Chair mentioned that this category would also likely to be focused on PH patients, but asked for feedback on whether or not it should be limited to PH only. They also noted that this would be data that is collected and evaluated as time went on to identify a gradation of risk. The Vice Chair noted how this is collected frequently for PH and the research supports collecting this as a prognostic indicator. Members supported limiting this data collection to PH patients only.

Pericardial Effusion

The Chair suggested the inclusion of pericardial effusion as seen on an echocardiogram in PH patients. A member stated that any presence of pericardial effusion in PH patients would be seen as a prognostic indicator and suggested leaving it as a binary yes or no data collection. The Subcommittee supported this collection for pericardial effusion and recommended the data be updated periodically.

Mean Right Atrium Pressure (mRAP) >20mmHg within one year

Members noted that some programs may run into issues if the expectation is that this is collected every year and explained that it is not uncommon for patients who have been already listed to not receive a RHC on a yearly basis. The Subcommittee agreed that the program should enter a date for reference but the value could be left as valid if it is older than a year.

Pulmonary Vascular Resistance (PVR) >32 wood unit (or >2560 dynes-sec/cm⁵)

The Chair suggested this data would be collected as part of the RHC and could enter the date along with all of the other RHC values. The Chair also asked if this value should eventually be mandatory for all candidates or only PH patients and members felt this is a prognostic indicator for all diagnoses groups. A

member did clarify that RHC data is not always available for pediatric candidates. The Vice Chair asked what is entered for RHC data for pediatric candidates and the Chair noted that there is an option to enter that it was not done. The member explained that this should be considered when proposing to make RHC data mandatory. UNOS IT clarified that none of the fields are mandatory outside of diagnosis, height, and weight in WaitlistSM and everything else is optional with some fields expiring because they are used in the lung allocation score (LAS) calculation.

Diffusing Capacity of the Lungs for Carbon Monoxide (DLCO)

The Subcommittee discussed if this should be the DLCO or “DLCO corrected” and the members agreed that the absolute value for the uncorrected value should be collected. SRTR staff and members agreed that the raw data would be more useful for informing potential trends and the system could calculate the present predicted or “DLCO corrected” so a consistent formula being used. The Subcommittee also supported that this data is entered in a way that is consistent with other PFT data. It was clarified that the categorizations listed above are also for risk factor stratification.

Recurrent pneumothoraces (RPTx)

A member asked for Subcommittee feedback on the appropriate time interval when defining RPTx and members felt that a month would be appropriate.

A member suggested that the variable be a dichotomous yes or no for any type of pleurodesis treatment without a time limit since you would want to know if a patient had a history of it. The Vice Chair noted that the aim of the collection was for Talc pleurodesis but acknowledged that knowing all types would be helpful. The Subcommittee supported collecting all types of pleurodesis (Talc, other chemical, mechanical, surgical, and chest tube (CT) placement only) without a time limit.

Bronchopleural fistula (BPF)

The Subcommittee discussed the collection as being a dichotomous variable of yes or no with a time of if present in the 12 months preceding transplant listing and felt it was appropriate. The Subcommittee felt that the types of pleurodesis treatments listed for RPTx should also be checkboxes here.

Frequency of exacerbations

The Vice Chair stated that there is so much objectivity in defining frequency of exacerbations and the Chair mentioned that when they submitted exception requests they collected the dates of exacerbations and the number of days on antibiotics. SRTR staff agreed that this is hard to define, but it is a good predictor of waitlist mortality so the data collection would have to be consistent with how it is defined, collected, and monitored. They also asked if at home antibiotic treatment would count and a member suggested it may be clearer to keep it at hospitalizations. Members agreed that hospitalizations would be appropriate. A member suggested hospital days and IV antibiotics be collected, and the Chair suggested the hospital days be specific to pulmonary exacerbation. Inclusion of this variable was discussed previously by the Committee as a gameable variable, however Subcommittee members felt that the variable is scientifically supported as a meaningful indicator and should be collected especially since it would only be captured for now. The Subcommittee also supported collecting the same data and having the same definition for all diagnoses groups.

Socioeconomic position (SEP)

SRTR staff asked if the inclusion of SEP has been considered since those data are some of the biggest predictors of survival, especially area deprivation index which relates to access to food and air quality. UNOS staff added that the research department recently started looking at data from LexisNexis®, but that data is very study specific so they are working to see if the data is clean enough to be used more

widely. SRTR staff asked if these data could be applied to all organ groups or if the organ groups should be thinking about it separately. UNOS staff clarified that the project is in very preliminary stages. The Subcommittee was asked what type of variable would be collected for this and both zip code and census zones were suggested, but privacy would have to be protected. The level of privacy was also discussed since the data collected and used would not be shared generally and we already collect a number of identifiers. SRTR staff stated that in order to accurately capture disparity we need to measure all aspects and incorporate it into the modeling. UNOS staff will look into the options for collecting these data.

Upcoming Meeting

- December 2022

Attendance

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