OPTN Lung Transplantation Committee
Updating Mortality Models Subcommittee
Meeting Summary
February 3, 2022
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 02/03/2022 to discuss the following agenda items:

1. Updated Mock-up and Data Element Review

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

1. Updated Mock-up and Data Element Review

The Subcommittee reviewed the updated Waitlist[SM] mock-up in detail and provided necessary clarification as needed following some feedback that was given by UNOS Member Quality staff.

Summary of discussion:

New York Heart Association (NYHA) Functional Classification vs. Functional Status [1]

The Subcommittee previously decided that NYHA Functional Classification should be added as a field for candidates with a Pulmonary Hypertension (PH)/Pulmonary Arterial Hypertension (PAH) diagnosis selected. Internal feedback requested clarification on whether or not both NYHA Functional Classification and Functional Status were necessary. The Chair clarified that the two fields are actually different and the NYHA Functional Classification is very specific to heart failure, including PH. They added that the intention with Functional Status is to capture the impact on the candidate's daily living. Subcommittee members agreed that both should be captured. The members were also asked if both fields are different enough to easily be entered by coordinators and the members felt that they would be and NYHA Functional Classification has defined classes that are documented.

Pericardial Effusion and Bronchopleural Fistula

The Subcommittee was asked for feedback regarding the timeframe for when this should be reported, specifically if they would be interested in if the candidate has ever experienced pericardial effusion and/or bronchopleural fistula or only if they are currently experiencing either. Members agreed that it should only be reported if the candidate is currently experiencing either pericardial effusion and/or bronchopleural fistula.

[1] 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

Clarification on reporting continuous positive airway pressure (CPAP) for sleep apnea

A topic that has come up as a clarification from transplant programs is whether or not CPAP should be reported if it is only used as treatment for sleep apnea. The Chair noted that they have also had the question come up, but that their program reports it since if the candidate is using CPAP, they are using CPAP regardless what it is for. They added that once a candidate gets to end stage lung disease it is also harder to differentiate if it is only being used for sleep apnea. The Vice Chair agreed that reporting it would be appropriate.

Definition of Intermittent Mechanical assisted ventilation

Another potential area for clarification that was recognized was the definition of "intermittent mechanical" for assisted ventilation. The Subcommittee was asked if there was a solid definition available and to confirm that none of the other options under assisted ventilation could be classified as intermittent. The Chair stated that they do not think it would be confused since intermittent means that the patient can spend time off of the ventilator and that really applies to people who can be at home. The Vice Chair mentioned that it may come up for patients using a Trilogy Ventilator and asked if other members would be putting it under intermittent, BiPAP, or mechanical. The Chair stated that their program puts them under intermittent since they have a lot of the same features of a ventilator, but agreed that Trilogy type devices should be clarified as intermittent in the guidance. A member asked if you could select more than one option, such as BiPAP and intermittent since the BiPAP is kind of intermittent. The Chair clarified that the difference is BiPAP would not be considered mechanical, so you would only be selecting what is appropriate. Another member stated that they have associated Trilogy devices more like a BiPAP, but recognized the rationale by putting them as intermittent mechanical. They also asked for clarification on whether or not other programs were using Trilogy devices only with a face mask or if they were also being used with a tracheostomy. Members clarified that Trilogy devices can be used with both a face mask and with a tracheostomy. The Vice Chair also added that Trilogy devices fall more under intermittent because of the settings and types of changes you can do with them.

A member asked how often "continuous mechanical – not hospitalized" is being utilized and stated that it seemed more appropriate to have "hospitalized" and "not hospitalized" options for intermittent mechanical since it would seem that those patients that are hospitalized would likely be sicker. The Chair added that if someone had to be hospitalized while on intermittent mechanical ventilation that it would likely be due to oxygen requirement. Members agreed that it would be appropriate to add "Intermittent mechanical – hospitalized" and "Intermittent mechanical – not hospitalized" as options for the "Assisted Ventilation" field.

Requires Supplemental O_2

Subcommittee feedback was requested for whether or not separate evaluation dates would be needed for at rest, with exercise, and at night or if one date for all three would be appropriate. Members initially felt that three separate dates would not be necessary. A member noted that currently you can only select one option, so it makes sense to have one date, but with the ability to input data for multiple options it might be helpful to have the evaluate dates for each. A member explained that there are instances where a patient will go up in their oxygen requirement during the day, but you have not updated their at night requirement so you would only be changing the evaluation date for one or two. A member asked if these separate dates would be an audit point for site surveys. UNOS staff clarified that since this is data that is only required to be updated every six months, are there situations where a patient's requirements are updated off of that six month cycle and if yes, would you update and report all three requirements or would you only do one or two so those would have different dates that would need to be verifiable. The Chair stated that the majority of the time you would have the same date, but

if a patient comes in and requires an update "at rest it would make sense to have the ability to enter a different date. A member also noted that some patients that may only have an “at night” requirement may change to also needing oxygen at rest which would need an associated date. Members agreed that while it may not be used very often, it would be best to have a separate evaluation date option for at rest, with exercise, and at night.

Subcommittee feedback was also requested on updating the “at night” option to be clearer that the intention is for when the patient is sleeping. Members supported changing the option to “with sleep” to make the choices more clear. UNOS Staff asked if the “at night”/”with sleep” option was necessary and the Chair clarified that a patient’s oxygen requirement while sleeping is different than at rest because there are patients that only need oxygen while sleeping which is different in how deeply someone is breathing than “at rest”. They also added that the intent with capturing these three options is capturing the difference between four patient types: those who do not require oxygen, those who only require it while sleeping, those who only require it with exertion, and those who need it at rest, which is essentially all the time.

Hemoptysis

The Subcommittee was asked for clarification on the timeframe that should be reported if a candidate experiences hemoptysis (i.e. should it be within the last year, all time, etc.). The Chair stated that the intention is to capture hemoptysis that is experienced in the prior 12 months from the date the information is being entered and members agreed.

The Subcommittee also clarified that they would like to only capture massive hemoptysis within the last 12 months with “massive hemoptysis” being defined the same as the CF Registry, “acute bleeding greater than or equal to 240mL in a 24 hour period or 100mL over several days”. Previous Subcommittee discussion also included that 8cc/kg in pediatrics would be appropriate for massive hemoptysis.[2] The Subcommittee also supported revising the mock-up to “Massive hemoptysis” rather than just “hemoptysis” so the intent behind the type of data collection is clearer.

Prior Lung and Cardiac Surgery and Pleurodesis

The Subcommittee discussed the options currently in the drop down on the mock-up for “Prior Lung Surgery” and if there was a need for “other, specify” similar to the “Prior Cardiac Surgery” field. The Subcommittee also discussed the need for “other, specify” fields for either field since those fields may yield messy data. Initially, the Chair supported removing the “other, specify” fields so that only the types of prior surgeries that are known to impact mortality are captured. SRTR Staff added that theoretically you should not force people into answers when surveying and wanted clarification on whether or not these fields are optional and how long it would take the OPTN Lung Transplantation Committee to update these fields if needed. It was clarified that these fields are optional but that any changes would need to go through public comment and OPTN Board of Directors approval like other data element changes. UNOS Staff asked if there was something else that this “other, specify” field could be called to be more clear and the Chair stated that essentially the intent is to capture if the patient had a procedure that went into the chest since that can lead to scarring and make lung transplant more difficult. The Subcommittee discussed the option of just “other” without the specify option and agreed that it would lead to more confusion if there was no option to specify what they are including and it would not be able inform future decisions. A member added that the simplest approach is the best from a transplant coordinator’s perspective. SRTR Staff noted that if there is a new procedure that is suddenly impacting

[2] OPTN Lung Transplantation Committee Updating Mortality Models Subcommittee Meeting Summary, September 23, 2021, accessed March 2, 2022, https://optn.transplant.hrsa.gov/media/32ibu3sq/20210923_lung-umm-subcommittee-meeting-summary.pdf

lung transplant outcomes, it would be beneficial to be able to capture that right away in an "other, specify" field. The Chair felt that data fields should be supported by the literature and SRTR Staff added that so much of the literature is founded in this database. The Chair asked if a research team would be able to look through the data from the "other, specify" field to see if there is anything relevant and SRTR Staff clarified that if there is a trend or new procedure they can pick up on that. Members agreed that they did not feel strongly on whether or not "other, specify" is included, but recognized it may be helpful and supported including the option for both prior lung and cardiac surgeries especially since any changes these fields will take time. Members also discussed options for guidance on this field and felt it would be straightforward to develop a list of procedures that should be excluded.

The Subcommittee was also asked for clarification on the timeframe for capturing when a candidate had a pleurodesis procedure and it was clarified that it should be reported if the patient ever had a pleurodesis procedure.

Availability of information for new data fields

The Subcommittee discussed how easily accessible these new data fields would be for transplant coordinators and it was mentioned that transplant programs have gotten good at understanding what needs to be clearly documented in order for it to be accurately reported in Waitlist[SM]. The Chair also added that these clinical issues are being discussed with patients so they should be documented in that patient's notes. SRTR Staff asked if there have ever been issues with documentation when a patient has been transferred to a new program and the Chair said that as long as the information is available in the clinical notes the coordinators can collect that, so it has not been an issue at their program. The Vice Chair also stated it has not been an issue at their program and that the new program is going to build on the information provided.

Upcoming Meetings

- April 7, 2022
- May 5, 2022

Attendance

- **Subcommittee Members**
  - Erika Lease, Chair
  - Marie Budev, Vice Chair
  - Dennis Lyu
  - John Reynolds
  - Marc Schecter
  - Whitney Brown
  - Staci Carter
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Katie Audette
  - Maryam Valapour
- **UNOS Staff**
  - Leah Slife
  - Sara Rose Wells
  - Tatenda Mupfudze
  - Holly Sobczak
  - Elizabeth Miller
  - Krissy Laurie
  - Liz Friddell