Meeting Summary

OPTN Lung Transplantation Committee Six-Minute Walk Workgroup Meeting Summary October 19, 2023 Conference Call Marie Budev, DO, Chair Matthew Hartwig, MD, Vice Chair

Introduction

The Six-Minute Walk Workgroup (the Workgroup) met via Webex teleconference on 10/19/2023 to discuss the following agenda items:

- 1. Welcome and agenda
- 2. Review and discuss draft proposal
- 3. Next steps and closing comments

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

1. Welcome and agenda

The Chair welcomed Workgroup members.

Summary of discussion:

There was no further discussion by the Workgroup.

2. Review and discuss draft proposal

The Workgroup reviewed a draft proposal that would remove standards for the six-minute walk test (6MWT) from policy and provide guidance to lung transplant programs on how to conduct an oxygen titration test and 6MWT. The guidance document recommends a separate oxygen titration test ahead of a 6MWT. A sample oxygen titration protocol is included as an appendix. It also recommends performing the oxygen titration test at least every six months. The proposed guidance document notes that the oxygen titration test may not be necessary before every 6MWT if oxygen needs are well-established and there are other challenges with completing the test, e.g. for pediatric candidates.

For the oxygen titration protocol, the proposed guidance document states:

At the conclusion of the oxygen titration test, record -

- Total time of the walk test
- Final dose of supplemental oxygen
- Candidate's final oxygen saturation (SpO2)
- Time walked on last supplemental oxygen dose prior to ending the test
- Ask the candidate to report a subjective level of dyspnea using the Borg scale at the end of the test

The proposed guidance document addresses safety considerations and recommends keeping most candidates at a SPO2 of 88% or greater during the 6MWT. It also notes that some candidates may be unable to maintain a SpO₂ of 88% or greater at rest but can still complete the 6MWT, so a lower threshold may be used. It recommends reporting a walk distance of 0 feet if a candidate is unable to

safely perform the test but encourages attempting the test if possible. The draft guidance document proposes a transplant program may submit an exception request under post-transplant outcomes if a candidate is unable to complete the walk due to reasons unrelated to lung disease.

The proposed data definition accompanying this proposal is:

Enter the total exertional distance on a flat surface the candidate is able to walk in six minutes in feet. <u>Refer to Guidance for Conducting the Six-Minute Walk Test for Lung Allocation for additional</u> <u>information on conducting the test.</u> The distance walked is a measure of functional status. The normal range is between 0 and 3000, although a value outside of <u>greater than</u> this range may be entered. Enter the Test Date when this information was obtained. These fields must be updated every 6 months from the time the candidate was added to the waiting list. If they are incomplete or expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.

The proposed guidance document would not be binding or required. This would be monitored through qualitative feedback from the community. There is no potential impact on select patient populations. The proposal will gather feedback from the community about:

- Do you support the policy and data definition changes?
- Is the guidance clear?
- Would you recommend any changes to the guidance?
- Does this proposal strike the right balance between promoting data quality for the six-minute walk distance and burden on lung candidates and lung transplant programs?
- What consideration should be given for altitude for candidates who live at a significantly different altitude compared to the transplant hospital where they are registered?

Summary of discussion:

Decision #1: The Workgroup agreed the guidance should not be too specific on oxygen delivery device, method of transporting oxygen supply, or type of nasal cannula used to supply oxygen.

Decision #2: The Workgroup agreed not to include suggestions in guidance for documenting information that is not reported to the OPTN (e.g. total time of walk test, subjective level of dyspnea, etc.).

Decision #3: The Workgroup agreed the final dose of supplemental oxygen from the oxygen titration protocol should be provided to the candidate when completing the 6MWT.

Decision #4: The Workgroup agreed the expectation is to not titrate during the 6MWT, but if the candidate desaturates, titrating during the test should be allowed.

Decision #5: The Workgroup agreed exception requests should be submitted if a candidate is unable to walk due to reasons unrelated to lung disease, but otherwise candidates who are unable to walk should report a walk distance of '0.'

Decision #6: The Workgroup agreed with striking 'the distance walked is a measure of functional status' from the data definition.

The Workgroup discussed if it is beneficial to specify whether pulling or pushing oxygen supply throughout the test. Members agreed it is best to leave language broad. Members stated some candidates will not be able to titrate up to a SpO2 of 89%, even at rest. Members agreed that limiting asks and requirements for unnecessary information will make the guidance document more readable. A member suggested adding guidance on how pediatric candidates handle the 6MWT when they are unable to carry their oxygen supply. A member noted that pediatric transplant programs are

accustomed to accommodating pediatric candidates in completion of the test so additional guidance may not be needed. Members agreed separating guidance by diagnosis group will be too detailed for this document. Workgroup members stated they are most comfortable with having a SpO2 threshold of 88%.

A member asked why the 6MWT is recorded in feet instead of meters. Members noted meters are referenced in literature and other countries. Another member stated it varies across different labs and transplant programs whether feet or meters are used.

Several members suggested an oxygen titration test should be required by policy before a candidate's first 6MWT. It could then be recommended afterward if oxygen needs have changed. Members suggested asking the community if the oxygen titration test should be required at all or if the oxygen titration test should be required at all or if the oxygen titration test should be required before every 6MWT.

3. Next steps and closing comments

The Lung Committee will review the proposal on 10/27/23. The Lung Committee will vote on sending the proposal to January 2024 public comment in their November meeting. The Lung Committee will discuss whether an oxygen titration test should only be in guidance or if at least one oxygen titration test should be required by policy.

Summary of discussion:

There was no further discussion by the Workgroup.

Upcoming Meetings

TBD

Attendance

• Workgroup Members

- o Marie Budev
- Cynthia Gries
- o Aleksander Tomas
- o Abby Motz
- o Julia Klesney-Tait
- o Dennis Lyu
- o Erika Lease
- o Katja Fort Rhoden
- o John Reynolds
- o Wayne Tsuang
- HRSA Representatives
 - o Jim Bowman
 - o Marilyn Levi
- SRTR Staff
 - o Katherine Audette
 - o David Schladt
- UNOS Staff
 - o Kaitlin Swanner
 - o Taylor Livelli
 - o Chelsea Weibel
 - o Sara Rose Wells
 - o Krissy Laurie
 - o Laura Schmitt
 - o Leah Nunez