Meeting Summary

OPTN Lung Transplantation Committee Six-Minute Walk Workgroup Meeting Summary August 24, 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 8/24/2023 to discuss the following agenda items:

- 1. Welcome and agenda
- 2. Recap and objectives
- 3. Oxygen titration protocols
 - UPMC
 - Duke
 - Discussion
- 4. Project options
- 5. Next steps and closing comments

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

1. Welcome and agenda

The Chair welcomed Workgroup members. Staff encouraged Workgroup members who are not members of the OPTN Lung Transplantation Committee to submit public comment as individuals on the proposal <u>Modify Lung Allocation by Blood Type.</u>

Summary of discussion:

A Workgroup member noted that scaling up to five points for blood type O candidates may be an overcorrection based on how it compares to the 95th percentile of points awarded for medical urgency. The Chair urged the member to read the proposal to see why the Committee went with this adjusted rating scale over others.

2. Recap and objectives

The Workgroup had previously decided to explore two paths forward:

- Additional data collection for two six-minute walk tests (6MWTs)
 - One test for medical urgency
 - One test for post-transplant survival
- Guidance on performing an oxygen titration test prior to the 6MWT

The Workgroup previously requested to review the University of Pittsburgh Medical Center's (UPMC) oxygen titration protocol. The Workgroup examined different oxygen titration protocols and continued to assess the two path forwards discussed in the previous meeting.

Summary of discussion:

Decision: There were no decisions made by the Workgroup.

There was no further discussion by the Workgroup.

3. Oxygen titration protocols

The <u>2014 AST/ERS standard</u> explicitly states the 6MWT used for distance assessment should not also be used for oxygen titration as they interfere with each other's assessment. The Workgroup has the opportunity to incorporate an oxygen titration test into guidance or into additional data collection.

• UPMC

The purpose of the oxygen titration protocol that was disseminated to the workgroup is to identify the highest capable exertion. The test is administered at three levels: at rest, at usual pace, and at exercise. The patient will then be walked for three minutes and whichever level of oxygen the patient is given during the oxygen titration test will be administered with the intention that the patient will stay above 90% oxygen saturation (SPO2) for at least three minutes. The patient is then increased by 2% elevation on the treadmill every two minutes until they reach a grade of 12%.

• Duke

This protocol involves a patient walking on a flat 30-meter course at a vigorous pace for at least six minutes. Testing concludes at six minutes if no desaturation occurs. If the patient desaturates to an SPO2 of 88% or less, supplemental oxygen is administered beginning at 2 L/min until SPO2 is 90% or greater. The patient stabilizes at this level for two minutes and then resumes walking until at least six minutes of walking has occurred and the oxygen dose has remained unchanged for three minutes. The test administrator will switch to a wide-bore nasal cannula at 8 L/min. The test is terminated if the patient is unable to maintain SPO2 above 88% at 15 L/min for three minutes.

Summary of discussion:

Decision: There were no decisions made by the Workgroup.

UPMC staff noted that they could provide another oxygen titration protocol that is more tailored to performing the 6MWT, and that the oxygen titration test and 6MWT are performed at least one hour apart. The Chair asked whether a treadmill is used for a 6MWT. UPMC staff responded no. The Chair asked if UPMC's transplant team goes higher than 15 liters of oxygen. UPMC staff responded that this is the protocol for oxygen titration tests in their lab but would alter this based on physician guidance. The Chair asked UPMC staff if it would create a burden for laboratories if the OPTN were to require two separate walks on the same day. UPMC staff stated they would find a way to accommodate this if that is the requirement.

The Chair asked a Workgroup member if idiopathic pulmonary fibrosis (IPF) patients can increase up to 25 liters of oxygen to maintain SPO2 greater than 88%. The member responded they stop at 15 liters.

4. Project options

Decision #1: Members agreed two tests will be incorporated in whichever path forward the Workgroup chooses.

Staff explained data collection could be implemented to collect two different 6MWTs. The data definition in the OPTN Computer System could advise on how to administer both tests. Guidance for different aspects of the 6MWT could include a recommended oxygen titration test ahead of the 6MWT with a recommended protocol. Guidance could outline when an oxygen titration test may not be necessary or feasible. Guidance could explain when it may be reasonable for patients to fall below the 88% SPO2 threshold (e.g. based on diagnosis). OPTN guidance could also recommend a device for supplying oxygen during a 6MWT. Guidance could include direction on exception requests that can be submitted if a candidate cannot walk.

Members agreed they could not move away from two tests regardless of project options, where two tests refers to one oxygen titration protocol and one 6MWT. Some members also favored options that may include multiple 6MWTs.

Summary of discussion:

Decision #2: The Workgroup will explore three options in future meetings. Option 1 – One oxygen titration test and one 6MWT Outline a standard oxygen titration protocol designed to determine oxygen needs for performing the 6MWT o This value would be entered as supplemental oxygen needed with exercise • This oxygen level would be used for conducting the 6MWT; titration during the test not permitted Option 2 – Two 6MWTs with separate oxygen requirements o 6MWT #1: Uses minimum oxygen (The Workgroup would need to determine whether "minimum oxygen" is "at rest" oxygen or minimum required to complete 6MWT) Intent is to capture disease severity • 6MWT #2: Uses maximum oxygen (The Workgroup would need to define this e.g. using nonrebreather or based on UPMC exercise protocol) Intent is to assess frailty/strength The Workgroup would need to select one of these tests for incorporation into the allocation score while collecting data Option 3 - Two 6MWTs, one "current" and one "standard" 6MWT #1: Allow transplant programs to keep doing whatever they are doing now; this value would feed into the allocation score o 6MWT #2: New data collection following a standard approach for supplemental oxygen provision

Members suggested one test would be administered with minimum required oxygen and one test would be administered with maximum oxygen. A member suggested an oxygen titration test should be administered to determine oxygen titration needs for the 6MWT. A member said two tests should be used to measure waitlist urgency and post-transplant survival because having one test result factor into both scores is not an accurate way to represent disease severity and functional status. A member suggested an oxygen titration test would be administered prior to two 6MWTs that factor into the composite allocation score (CAS).

Members agreed data collection for multiple tests may be needed to later refit the medical urgency and post-transplant survival models. In the interim, the Workgroup would need to decide which test should factor into the CAS. A member stated a test with minimum oxygen administered that factors into the waitlist urgency score and a test with maximum oxygen administered that factors into the post-

transplant survival score could be done now. UPMC staff noted minimum oxygen required would be difficult to standardize, particularly if some patients cannot complete the test without additional oxygen support. A member suggested transplant programs could choose the test that benefits their candidates' scores the most.

5. Next steps and closing comments

The Chair thanked members for joining.

Summary of discussion:

There was no further discussion by the Workgroup.

Upcoming Meetings

• September 28, 2023, teleconference, 5pm EST

Attendance

• Workgroup Members

- o Marie Budev
- o Cynthia Gries
- o Aleksander Tomas
- o Brian Armstrong
- o Dennis Lyu
- o Erika Lease
- o John Reynolds
- o Wayne Tsuang
- HRSA Representatives
 - o Jim Bowman
- SRTR Staff
 - o Katherine Audette
 - o David Schaldt
- UNOS Staff
 - o Kaitlin Swanner
 - o Taylor Livelli
 - o Chelsea Weibel
 - o Darby Harris
 - o Laura Schmitt
 - o Sara Rose Wells
- Other Attendees
 - o Frank Sciurba