OPTN Lung Transplantation Committee
Six-Minute Walk Workgroup
Meeting Summary
April 6, 2023
Conference Call
Marie Budev, DO, Chair
Matthew Hartwig, MD, Vice Chair

Introduction

The Six-Minute Walk Workgroup (the Workgroup) met via Citrix GoTo teleconference on 4/6/2023 to discuss the following agenda items:

1. Welcome and agenda
2. Project overview, scope, and timeline
3. Discussion
4. Next Steps and Closing Comments

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

1. Welcome and agenda

The Chair welcomed Workgroup members and presenters.

Summary of discussion:

There was no further discussion by the Workgroup.

2. Project overview, scope, and timeline

The Chair provided an overview of the six-minute walk test and project goal. She explained the Workgroup is made up of the OPTN Lung Transplantation Committee Chair, Vice Chair, Past Chair, patient representative, transplant educator, and pulmonologists. The Workgroup also consists of respiratory therapists and a member of the American Thoracic Society (ATS) Committee that develop the 2002 guidelines.

The Six-Minute Walk Test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes (the 6MWD) and provides quantifiable assessment of patient's functional exercise capacity. The test requires a 100-ft hallway but no exercise equipment or advanced training.

In lung allocation, the 6MWD factors into both the waitlist survival and post-transplant survival parts of the composite allocation score (CAS).

If patients travel zero feet or a short distance during the six-minute walk:

- Are more medically urgent and therefore higher waitlist survival score
- Have a lower post-transplant survival score

Patients who walk farther in the six-minute walk:

- Will not receive as many points for medical urgency
- Will receive more points in their post-transplant survival score

The Chair noted the American Thoracic Society (ATS) published guidelines on performing the six-minute walk[1] in 2002 and a technical standard in 2014.[2] The guidelines and technical standard are not specific to transplant and the performance of the six-minute walk is not consistent across transplant programs.

Some programs provide supplemental oxygen during the walk; others do not provide oxygen. Some programs titrate supplemental oxygen during the walk; some provide only "at rest" levels. Some programs do a practice walk or titration walk first.

The Chair explained the goal of this project is to standardize how transplant programs perform the six-minute walk for the purposes of OPTN data collection since it impacts lung allocation. This will help to ensure lung candidates are appropriately prioritized for lung transplant based on their estimated waitlist and post-transplant survival. The Workgroup will consider changes to policy and data definitions and/or developing guidance to achieve this goal, while avoiding duplicating existing guidance. The Workgroup will focus on needs specific to OPTN.

Current OPTN Policy 10.1.A.1. Waitlist Survival Points for Candidates at least 12 Years Old states, "Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test."[3] The current data definition in the OPTN Computer System states:

- Enter the distance the candidate is able to walk in six minutes in feet.
- The distance walked is a measure of functional status.
- The normal range is between 0 and 3000, although a value outside of 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 Waitlist.
- If they are incomplete or expired, the least beneficial value will be used to calculate the candidate's lung composite allocation score.

An update pending implementation will advise centers to enter the **total exertional distance on a flat surface** the candidate is able to walk in six minutes in feet.

The Chair outlined the projected timeline for the project as:

- September 2022
    - OPTN Data Advisory Committee review

[1] "Guidelines for the Six-Minute Walk Test." American Journal of Respiratory and Critical Care Medicine 166, no. 1 (2002): 111–17. https://doi.org/10.1164/ajrccm.166.1.at1102.
[2] Anne E. Holland, Martijn A. Spruit, Thierry Troosters, Milo A. Puhan, Ve´ronique Pepin, Didier Saey, Meredith C. McCormack, Brian W. Carlin, Frank C. Sciurba, Fabio Pitta, Jack Wanger, Neil MacIntyre, David A. Kaminsky, Bruce H. Culver, Susan M. Revill, N. "An Official European Respiratory Society/ American Thoracic Society ..." An official European Respiratory Society/ American Thoracic Society technical standard: field walking tests in chronic respiratory disease. ERS/ATS, October 30, 2014. https://www.thoracic.org/statements/resources/copd/FWT-Tech-Std.pdf.
[3] OPTN Policy 10.1.A.1.: Waitlist Survival Points for Candidates at least 12 years old (Accessed April 11, 2023) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

    - OPTN Policy Oversight Committee approval
    - OPTN Executive Committee approval
- April – October 2023
    - Workgroup develops proposal
    - Check in with OPTN Data Advisory Committee as needed
- November 2023
    - OPTN Lung Committee votes to send proposal out for public comment
- January 2024
    - Proposal goes out for public comment

Summary of discussion:

There was no further discussion by the Workgroup.

3. Discussion

The Chair asked for feedback on:

- Do you have any questions about the project goal or scope?
- Are there other concerns related to six-minute walk tests that should be explored by this workgroup?
- What other references/literature should the workgroup review?
- What other information do you need to inform this work?
- Do you have recommendations for how the workgroup should proceed?

Summary of discussion:

The Past Chair commented that altitude can be a factor in how candidates perform in their six-minute walk test. She stated this could be accounted for in the system. Members agreed. A member asked how much supplemental oxygen candidates should receive.

A member stated the initial question is whether the six-minute walk is an indicator of functional status or severity of lung disease. The member stated it is currently used for functionality. She stated then the Workgroup can address the amount of supplemental oxygen candidates should be given during the test. A member stated program variability on conducting the six-minute walk tests is the issue, but the Workgroup needs to better understand what programs are doing. A member stated the six-minute walk test and an oxygen titration test are two different tests that cannot be done simultaneously. Oxygen titration tests are used to determine what level of oxygen is needed for the candidate to stay saturated for six minutes or longer. The 6MWD takes a candidate at rest and walks the candidate for six minutes, with the only cutoff happening if a candidate drops below 80 percent of oxygen. The member stated 2 L/min oxygen was a standard used in clinical trials with a hard stop at 80 percent of oxygen.

A member suggested that candidates should receive a desaturation study prior to the six-minute walk test. Members agreed, but cautioned centers may be against this since it requires two tests. A member noted a shorter distance will result in a higher CAS. The member stated baseline hypoxia and distance are the only current factors for six-minute walk tests, but other factors need to be incorporated. A member agreed and said exertion requirements need to be factored in as well. He argued that providing

high levels of oxygen may result in a lower medical urgency score that is not reflective of a candidate's condition.

A member stated that a lot of centers are using pendulum rebreathers. A member agreed that delivery of oxygen is device specific, so the Workgroup needs to be cognizant of that. A member stated the Workgroup needs to decide what the six-minute walk is used to determine. He noted if that is functional capacity, oxygen will be used as an equalizer or if that is disease severity, that would involve no equalizer at any time. Procedurally anything is possible. The Past Chair stated CAS considers amount of oxygen and distance, so two tests may be required. A member stated the six-minute walk test is used to look at functional capacity of candidates, which means supplemental oxygen should be less of a factor. A rebreather can be used to make sure a candidate is able to walk on a flat surface. She stated if candidates are unable to walk, it shows their deconditioning, rather than their severity of illness. Severity of illness is captured by pulmonary hypertension, lung function, etc. There is a lot of variability in a candidate's deconditioning, and the six-minute walk test is a measure of frailty.

The member stated a way to avoid using two tests is to have candidates walk on 100 percent nonrebreather to create consistency. The Past Chair stated the allocation system would need to be changed to do that because of the way oxygen is currently incorporated.

The Chair suggested surveying centers to see how they are conducting these tests and ask for sentiment on conducting two tests. A member agreed it would be helpful to learn more about what transplant programs are doing now. A member stated if two tests are conducted, the system should allow for distance and oxygen to be inputted and distance and oxygen should allow a candidate to gain points under CAS. The Past Chair stated that at rest, at sleep, and at exercise oxygen levels will be able to be entered into the system in 2024, so oxygen data collection is changing. However, at this time, supplemental oxygen needs can only be entered for one of these activity levels. She stated that distance can be a separate data point. Members agreed.

A member noted the weight of the six-minute walk is based on historical data. She stated she does not know how to weigh this walk without the backing of data. The Past Chair agreed the weighting will not be able to change until additional data are collected and the Committee proposes a policy change. The member agreed and stated variability is the first issue to tackle and what should optimally be measured through the six-minute walk test is a later problem to solve. Members agreed. A member stated that the coefficient will change over time with CAS and that surveying centers on current practices will not show the ways in which centers are taking advantage of this variability. She stated that there are enough people on the Workgroup to inform the variability. The Chair noted that larger centers are less likely to deviate from protocols. Another member stated that a survey will allow for better adaptability and compliance. The current scope of variability is not understood.

A member suggested that the policy language needs to be modified because it says the 6MWD should be obtained while the candidate is receiving supplemental oxygen based on their needs at rest, and the member did not think that was right, particularly for idiopathic pulmonary fibrosis candidates. The Chair suggested providing the community with options on how to perform the six-minute walk and see which solicits the most support. Members agreed. A member suggested asking the community if the six-minute walk should be used to measure functional status.

A member stated the younger the candidate, the more variability in the walk. She stated that pediatric candidates are often on lower amounts of oxygen and a variety of oxygen delivery methods. She noted pediatric programs are usually measuring functional status through the six-minute walk, but conducting the test is more difficult in pediatric candidates since they require more direction and encouragement to complete the test in accordance with protocols.

A member stated sticking to the 2014 guidelines is the most challenging. He noted this would involve not titrating during the six-minute walk and deciding what level of oxygen candidates will receive. A member responded that pediatric candidates cannot be thrown on room air or nonrebreathers because of shunting. A member stated this is the same for a pulmonary hypertension candidate and a chronic obstructive pulmonary disease (COPD) who cannot always be put on nonrebreathers and room air.

A member suggested candidates walk on a treadmill and maintain oxygen level for two minutes at different inclines on the treadmill to get a sense of oxygen needed for daily activities at home. This shows what oxygen level candidates need on flat surfaces. A member stated his center tries to capture an at rest oxygen titration and then conduct the six-minute walk test on that level of titration. The Chair voiced concern over sick candidates not receiving optimal oxygen, and therefore not performing at their optimal functional status.

A member questioned why the Workgroup would equalize oxygen used in the six-minute walk test because that is a characteristic of lung disease. He suggested instead using the traditional cutoff of 80% and using the at rest oxygen level of a candidate. A member said that how much oxygen a candidate needs at rest does not indicate severity of disease, but rather oxygen needed at rest and exertion both should be factored. A member stated that is the two-test argument. Members agreed.

A member stated that as a recipient he has completed many six-minute walk tests. He noted that environment in a hallway (e.g. number of people to avoid), hallway distance, devices used, number of turns, and number of questions asked by a test conductor are all factors that can affect a candidate's performance on the six-minute walk test. He emphasized the need to ensure candidate comfort. He said that fewer tests are better for candidates.

The Past Chair stated device variability is important. A member noted the center location should not necessarily be where the test is conducted if altitude is a factor.

4. Next Steps and Closing Comments

The Chair thanked the Workgroup for the discussion.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meetings

- April 27, 2023, teleconference, 5pm EST

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Abigail Motz
  - Aleksander Tomas
  - Brian Armstrong
  - Cynthia Gries
  - Dennis Lyu
  - John Reynolds
  - Julia Klesney-Tait
  - Kevin McCarthy
  - Nirmal Sharma
  - Soma Jyothula
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Nicholas Wood
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Krissy Laurie
  - Tatenda Mupfudze
  - Samantha Weiss
  - Chelsea Weibel