OPTN Lung Transplantation Committee Six-Minute Walk Workgroup Meeting Summary May 25, 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 5/25/2023 to discuss the following agenda items:

- 1. Welcome and agenda
- 2. Possible approach to policy language
- 3. Guidance for severely impaired patients
- 4. Considerations for altitude
- 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.

Summary of discussion:

There was no further discussion by the Workgroup.

2. Possible approach to policy language

The Committee discussed a possible update to policy language that would help clarify standards for the Six-Minute Walk Test (6MWT).

- Current language states:
 - Six-minute-walk-distance (feet) obtained while 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.
- A possible update:
 - Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of <u>80%</u> or greater at rest. <u>Supplemental oxygen needs must be determined prior to obtaining the six-minute-walkdistance and supplemental oxygen must not be titrated during the test.</u>

The Workgroup discussed whether they agree the oxygen saturation threshold in policy should be lowered to 80% to align with the 2014 ERS/ATS technical standard¹ and whether they support a less prescriptive approach to policy.

Summary of discussion:

Members vocalized concern over lowering the standard of oxygen saturation to 80%. The Past Chair stated that is not reflective of what is happening in patients' lives. She stated this is focusing on oxygen requirements as an indicator of severity of illness, so she would not feel comfortable doing this with her own patients. The Chair stated it is difficult to recover patients who drop down to 80% oxygen saturation so they can continue to walk. She stated this puts patient at risk. A member noted those with pulmonary hypertension can suffer greatly from this practice.

A member asked about patients that cannot achieve 80% oxygen saturation despite titration. He suggested refining policy language to encompass patients with congenital disorders. He does not want them to be excluded from the test. A member asked if the purpose of the 6MWT is to measure severity of illness or functional status. She said that if patients cannot keep their stats above 88% their distance should be zero. If the 6MWT is a marker of current strength letting patients drop lower is appropriate. A member said the 6MWT currently is used as a measure of both severity of illness and functional status.

The Past Chair commented it is challenging to capture both severity of illness and conditioning with the same test, since the six-minute walk distance (6MWD) is in the calculation for post-transplant survival and waitlist mortality. The Chair highlighted that entering a zero feet 6MWD disadvantages candidates under the composite allocation score (CAS).

A member asked if it is possible to create a pathway that would allow for patients with congenital heart disease to fall below 88% and continue the test. The Past Chair stated her program documents when specific patients cannot get an oxygen saturation up to 88%. The Chair stated her program titrates these patients starting at two liters and then increases by one liter until they reach 92% oxygen saturation. She agreed some patients will never reach their threshold when walking or at rest.

A member vocalized concern over leaving the amount of supplemental oxygen up to the program resulting in the consistent lack of standardization. She suggested requiring programs to walk patients on 100% fraction of inspired oxygen (FiO2) and then measuring the distance walked in six minutes. The member asked what might be the downside to this approach. A member responded it is difficult to keep patients on a maximum level of oxygen, even with a nonrebreather mask. This also affects patient comfort for those that do not have a large supplemental oxygen need. He also noted it is easy to run out of oxygen using laboratory devices. The member was concerned about embracing this approach for every patient. A member suggested differentiating between outpatients who probably can stay above 88% and inpatients who will have higher oxygen needs. She stated policy could require a desaturation study to keep stats above 88% on ambulation and if a patient is unable to do this, they will walk on 100% FiO2. A member stated it may be worthwhile to standardize the oxygen device used for inpatient versus outpatient definition. Members agreed.

The Past Chair noted oxygen at rest and oxygen with exertion data collection will be implemented in 2023 with the <u>Update Data Collection for Lung Mortality Models</u> proposal.

¹ Anne E Holland, Martijn A. Spruit, Tierry Troosters, et al., "An official European Respiratory Society/American Thoracic Society technical standard: field walking tests in chronic respiratory disease," European Respiratory Journal 44 (2014): 1428-1446, DOI: 10.1183/09031936.00150314.

A member stated his program asks candidates what amount of supplemental oxygen they are using during pulmonary rehabilitation and then uses this oxygen level during the 6MWT. He stated this should be left up to the centers on how to adequately provide oxygen. The Past Chair stated that is sufficient when trying to determine distance, but an oxygen titration study will help note exactly what is needed on exertion.

The Past Chair stated programs will need to do two walk tests when first being evaluated: one walk to determine oxygen need and then one walk to determine distance. She suggested two walks would not be necessary if oxygen needs have not changed in between visits.

The Chair emphasized the Workgroup needs to examine protocols from other programs. Members agreed the language suggested is too vague.

3. Guidance for severely impaired patients

The Workgroup discussed whether standards should be set for when to report zero for the 6MWD for the purposes of lung allocation versus attempting the test. They also discussed ERS/ATS standard contraindications and whether there are transplant-specific considerations that the standard does not capture.

Summary of discussion:

The Past Chair stated the listed contraindications would not allow a patient to become a candidate, and she thinks selecting zero feet should be left up to the discretion of centers. A member commented 10-foot markings are put into her center's floor to make sure the 6MWT is standardized and consistent.

A member commented severe hypercapnia should be included as a contraindication, as a significant change from patient baseline could be considered a contraindication unique to lung transplant candidates. A member responded it would not be correct to enter a zero, but instead provide guidance on how to administer a walk in these situations. Another member commented it should only be zero feet entered for distance if a candidate is on a ventilator, on extracorporeal membrane oxygenation (ECMO), or a program does not feel it is safe to walk a candidate.

Staff asked members what programs should do in instances where a candidate cannot walk due to issues unrelated to lung disease. Members agreed programs should submit an exception request for these situations. Staff asked if members had used a comparable exertion exercise instead of walking for the 6MWD. A member stated he has used a hand odometer and a pedal for a candidate previously. A member stated a patient who was wheelchair bound required the use of an ergometer to measure supplemental oxygen needs.

4. Considerations for altitude

Staff noted a study conducted in Peru found the 6MWT predicted a lowered functional capacity among Andean high altitude versus sea level natives at their altitude of residence.² She emphasized this could be explained by an incomplete adaptation or a protective mechanism favoring neuro- and cardioprotection over psychomotor activity. A study in Brazil found altitude did not affect the

² Caffrey D, Miranda JJ, Gilman RH, Davila-Roman VG, Cabrera L, Dowling R, Stewart T, Bernabe-Ortiz A, Wise R, Leon-Velarde F, Checkley W; CRONICAS Cohort Study Group. A cross-sectional study of differences in 6-min walk distance in healthy adults residing at high altitude versus sea level. Extrem Physiol Med. 2014 Feb 1;3(1):3. doi: 10.1186/2046-7648-3-3. PMID: 24484777; PMCID: PMC3909455.

performance of the walking test in patients with moderate to severe pulmonary disease and the results were similar in both cases, on sand and on asphalt.³

The Workgroup discussed whether there should there be a conversion or guidance to account for altitude.

Summary of discussion:

The Past Chair stated candidates doing their walk tests at sea level who do not live at sea level need less oxygen when coming to the transplant program for their assessment. A member stated the equalizer should be the amount of oxygen saturation candidates maintain. A member stated entering oxygen levels at rest should not necessarily affect the 6MWT. If candidates are on the same amount of oxygen, it should not affect their distance no matter where they are walking. He questioned if partial pressure of oxygen should be adjusted for altitude.

A member noted the amount of oxygen required at rest is currently a marker of severity of illness, since that is entered into the system for the purposes of allocation along with the 6MWD. She said that a correction should be made for oxygen at altitude. She suggested someone with pulmonary fibrosis needs more oxygen at rest with disease progression, so oxygen plays a large role at listing. Candidates who live at higher altitudes will have an advantage over candidates who live at sea level. The Past Chair agreed and stated the candidate on oxygen at higher altitudes will receive priority. Members noted that future iterations of the CAS may include oxygen at rest, at night, and with exertion. Most transplant programs are currently entering oxygen at rest.

5. Next steps and closing comments

Staff will continue to collect more 6MWT protocols from different transplant programs.

Summary of discussion:

There was no further discussion by the Workgroup.

Upcoming Meetings

• June 22, 2023, teleconference, 5pm EST

³ Squassoni SD, Machado NC, Lapa MS, Cordoni PK, Bortolassi LC, Oliveira JN, Tavares CM, Fiss E. Comparison between the 6-minute walk tests performed in patients with chronic obstructive pulmonary disease at different altitudes. Einstein (Sao Paulo). 2014 Oct-Dec;12(4):447-51. doi: 10.1590/S1679-45082014AO3139. PMID: 25628195; PMCID: PMC4879910.

Attendance

• Workgroup Members

- o Marie Budev
- o Erika Lease
- o Abigail Motz
- o Aleksander Tomas
- o Cynthia Gries
- o Dennis Lyu
- o Julia Klesney-Tait
- o Kevin McCarthy
- o Matthew Hartwig
- o Nirmal Sharma
- HRSA Representatives
 - o Jim Bowman
- SRTR Staff
 - o David Schladt
 - Katherine Audette
- UNOS Staff
 - o Kaitlin Swanner
 - o Taylor Livelli
 - o Tatenda Mupfudze
 - o Samantha Weiss
 - o Sara Rose Wells
 - o Krissy Laurie
 - o Chelsea Weibel