Meeting Summary

OPTN Lung Transplantation Committee Six-Minute Walk Workgroup Meeting Summary July 27, 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 7/27/2023 to discuss the following agenda items:

- 1. Welcome and agenda
- 2. Review summary of discussions to date
 - Areas of agreement
 - Open questions
- 3. Review potential project options
 - Data collection changes
 - Guidance
 - Policy
- 4. Discuss next steps
- 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. Review summary of discussions to date

• Areas of agreement

The Workgroup agrees that a score of zero should be entered for the six-minute walk distance (6MWD) in instances where it is not feasible or safe to administer the test for a candidate. Exception requests should be considered for candidates that cannot perform the six-minute walk test (6MWT) due to reasons unrelated to lung disease. The Workgroup also agrees altitude should be factored into the 6MWT score but is still discussing how this should be incorporated.

• Open questions

The Workgroup has not reached a decision on whether one test is sufficient or if multiple tests are warranted for the 6MWT. The Workgroup is still discussing whether oxygen titration should be administered before or during the 6MWT. Additionally, the Workgroup has debated whether an oxygen saturation threshold of 80 versus 88 percent is appropriate.

Summary of discussion:

Decision #1: The Workgroup agreed the recap presented was an accurate representation of discussion in past Workgroup meetings.

3. Review potential project options

The Workgroup discussed pursuing guidance on performing the 6MWT, data collection of two data fields for 6MWD that allow one value based on maximum performance and one value based on disease state, and policy language changes.

• Data collection changes

Data collection would allow for one test for medical urgency score (ADL-level oxygen, reflect disease state) and one test for post-transplant survival score (max oxygen, reflect frailty). Once enough data is collected, the Committee would need to ask SRTR to refit the waitlist survival and post-transplant survival models. Refitting the models would determine the coefficients for use of separate 6MWD values in the waitlist survival score and the post-transplant survival score.

Guidance

Guidance would allow the Workgroup group to define an optimal approach without mandating it and to acknowledge that transplant programs may need to use discretion depending on the circumstances.

Policy

The policy language can be updated as needed to align with either data collection and/or guidance changes.

Summary of discussion:

Decision #2: The Workgroup decided additional data collection for two tests for the 6MWT for waitlist survival and post-transplant survival or providing guidance on performing an oxygen titration test prior to the 6MWT will be the best paths forward.

A member commented the 6MWT is weighted more in the waitlist survival score than the posttransplant survival score, so the Workgroup must be cognizant of that. A member stated two different tests are needed because of the nonlinearity of the waitlist survival score and to meet the needs of the composite allocation score (CAS). He cautioned bunching candidates' scores together based on oxygen needs only. The 6MWD helps differentiate this. A member noted the distance walked is not as important as capturing oxygen needs with ambulation. She explained the Workgroup needs to look for a marker of severity of illness that is not currently captured. The Chair agreed. The implementation of <u>Update Data</u> <u>Collection for Lung Mortality Models</u> will capture oxygen needed at rest, with sleep, and with exercise only. Members agreed without this data collected, guidance may be the best approach.

A member asked if oxygen needs are all that is needed for the waitlist survival score, then why the modeling historically included the 6MWD as well. Staff responded that both variables have shown to be predictive in the modeling, which is why both are included, though sometimes variables that are clinically significant may not show up as predictive in the model if they are accounted for by other variables in the model.

A member argued oxygen required with ambulation should be used to administer a 6MWT. The Chair suggested requiring a two-walk test. A member responded the margin on the waitlist survival score is so

small between candidates and requiring a standard 6MWT would lose that differentiation. The Chair responded transplant programs can conduct the test they are currently administering and then collect additional data on the standardized approach, but this would be a burden on candidates.

The Chair asked if data collection should be mandatory. Staff responded this could be considered through project development. The Chair stated the burden of requiring two data fields for two tests may be difficult for all transplant programs. Members said this is needed and should be required to change behavior. A member suggested a missing or expired value could be used when two tests are not done.

A member voiced concerns over two tests in the pediatric population. The member asked if a recovery window between tests could be specified. Members noted since policy assigns fixed medical urgency and post-transplant survival scores for pediatric candidates less than 12 years old, the 6MWD does not play a role in their scores at this time.

A member suggested six minutes are not needed for both tests, and the first test should be used as an oxygen titration study, which could be shorter in duration (e.g. three minutes). Members agreed shorter tests may be less daunting for candidates.

4. Discuss next steps

The Workgroup discussed information needed to inform future discussion.

Summary of discussion:

Decision #3: The Workgroup will review the 6MWT protocol used at the University of Pittsburgh Medical Center.

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

• August 24, 2023, teleconference, 5pm EST

Attendance

• Workgroup Members

- o Marie Budev
- o Cynthia Gries
- o Aleksander Tomas
- o Brian Armstrong
- o Dennis Lyu
- o John Reynolds
- o Abigail Motz
- 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 Samantha Weiss
 - o Susan Tlusty
 - o Chelsea Weibel