OPTN Lung Transplantation Committee
Meeting Summary
October 24, 2022
Conference Call

Marie Budev, DO, Chair
Matthew Hartwig, MD, Vice Chair

Introduction

The Lung Transplantation Committee (the Committee) met in-person in Chicago, IL on 10/24/2022 to discuss the following agenda items:

1. Review and discuss public comment feedback on Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution
    a. *Finalize proposal*
2. VOTE: Do you support sending Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution to the Board of Directors in December 2022?
3. Review and discuss public comment feedback on Update Data Collection for Lung Mortality Models
4. Finalize Mortality Models proposal
5. VOTE: Do you support sending Update Data Collection for Lung Mortality Models to the Board of Directors in December 2022?
6. Donation After Circulatory Death (DCD) Lung Transplant Collaborative
7. Heart ABOI Project Update
8. Demonstration: Phase 1 implementation for continuous distribution of lungs
9. Discuss NASEM recommendations
10. Next Steps and Closing Comments

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

1. Review and discuss public comment feedback on Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution[1]

a. Finalize proposal

UNOS staff presented on the background of the proposal:

- There is a new Lung Review Board for continuous distribution (CD) of lungs
- The CD proposal included policy language for the review board
- This proposal includes updates to policy, clinical guidance, and operational guidelines
- Since all organs will need to make updates for CD, a common framework was established to use across organs
- Organ-specific committees may adjust the framework as needed to reflect unique aspects of transplantation for that organ

[1] "Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution," OPTN, accessed November 19, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/revise-lung-review-board-guidelines-guidance-and-policy-for-continuous-distribution/.

- The policy established the review board and sets basic requirements for appeals process
- The operational guidelines include most of the details about how the review board operates
- The clinical guidance is non-binding guidance for the review board and transplant programs on specific clinical considerations

UNOS staff also gave an overview of the voting process for CD:

- Day 0: Transplant program submits exception request
- Day 1-3: Review board members review and vote
- Day 4: If members have not voted case will be reassigned to another primary reviewer (or alternate if primaries are out of office) and notification will be sent
- Day 5: End of review period
- Voting will close at the earliest when:
    - A majority of all eligible votes have voted to approve an exception request
    - A majority of all eligible voters have voted to deny an exception request
    - The 5-day review period ends

If the majority votes to approve, the request is approved. If the majority vote to deny, the request is denied. If there is a tie, the request is approved. If no votes are submitted, the request is approved.

- Quorum/minimum number of voters is not required for CD
- In the current system, a large majority of cases close within review time period, which means the cases received enough reviewers/votes prior to the expiration of the review period

There was feedback from the public regarding pediatric exception requests. They voiced concern over pediatric reviewers being minorities on pediatric cases. Suggestions included establishing a separate pediatric lung review board or adding more pediatric experts to the existing review board and assigning only pediatric specialists to pediatric cases who have real and contemporary pediatric experience. Others supported ensuring there are at least 3 pediatric reviewers per case.

There was additional feedback from the public that rather than having a set number of reviewers, have a set percentage to account for changes over time. Other feedback included considering geographic location, program size, and adult and pediatric expertise. There was mixed feedback regarding whether the chair of the Review Board should be a voting member.

Feedback regarding voting included requiring a quorum with a minimum of five members. Additionally, the transplant community urged that timeline be limited, with suggestions including five days, three days, and defaulting to an alternate voter when a primary does not respond. UNOS staff explained that the first day the case is sent out counts as day zero, so reviewers will have three full days to respond.

The public suggested submitting appeals within seven days instead of 14 with language that is understandable for patients. Feedback also asked for educational offerings for the community and candidates.

<u>Data Summary:</u>

From January 1, 2022-March 31, 2022, most cases were closed within 5 days. From January 20, 2021-October 14, 2022, most cases were closed within two days.

This proposal was supported throughout regions with one opposed sentiment in Region 5, which was provided by a transplant hospital representative who expressed concern about pediatric representation for review of pediatric cases

<u>Summary of discussion:</u>

The Committee supported clarifying in the operational guidelines that it is up to the transplant program, rather than the OPTN, to ensure that their review board members meet the experience requirements. The Committee also added a requirement for any member of the Committee who reviewed a case as a review board representative to abstain from voting on an appeal to the Committee.

Pediatric Representation

The Chair asked UNOS staff to go over pediatric representation. UNOS staff explained the requirement is to have 12 review board members with at least three having an active pediatric lung transplant component. The Chair noted the lung community is limited by the number of pediatric programs performing lung transplant. A member commented there are only 6 or 7 true pediatric programs with 1 or 2 pulmonologists. This is very limited. He stated that having a separate board would mean that pediatric providers would lose the opportunity to extrapolate information from adult cases. Adult input may be beneficial for pediatric cases as well.

A member asked how many of pediatric transplant candidates need exceptions. UNOS staff responded that there was only one exception request for a candidate under the age of 12 in the last two years, and there are only 29 pediatric candidates at 11 programs listed.[2] A member stated some pediatric reviewers may not be comfortable reviewing cases for all age groups. The Chair suggested these reviewers must have completed a certain number of pediatric transplants in a year. Another member suggested an age cutoff because several adult surgeons have transplanted minors who qualify as pediatric because they are younger than 18 but their physiology is much more like adults. He noted the pediatric reviewers need to understand the physiology for candidates under the age of 12.

A member stated her experience on the board has led her to wait for a pediatric reviewer to vote on a pediatric exception before she votes. A member stated that if one pediatric exception a year is auto approved due to a lack of reviewers, this will not be detrimental to the system. The Chair noted reviewers will not be able to see other reviewers' votes so reviewers will not see when pediatric reviewers have voted. Members stated this may be problematic and they enjoy seeing how others vote. The Chair explained she requested that reviewers cannot see others' votes to prevent biases.

A member suggested letting members have the option to abstain from a pediatric case. UNOS staff explained they can opt to be reassigned and the case will be assigned to another reviewer. Members suggested requiring reviewers' programs have completed a pediatric transplant in the past three years to be less restrictive. A member suggested five years to account for movement between programs. He suggested a pediatric surgeon could be the alternate when a pulmonologist is not available. Members agreed.

UNOS staff explained 10-12 pediatric transplants are done a year. Members also noted there are not specific requirements for lung pediatric transplant. Members emphasized the need for adult perspective on pediatric cases, especially since a pediatric reviewer cannot review a case if their center submitted the exception request. Members suggested prioritizing pediatric reviewers' votes over others. UNOS staff responded this is not possible from a system perspective, but pediatric reviewers could be most of the reviewers on pediatric cases. Members suggested having five reviewers on pediatric cases with three pediatric reviewers and two adult reviewers so that the pediatric reviewers would make up the majority.

Members stated that having a separate pediatric review board will be an intense time commitment since there are likely only 8 programs that regularly perform under 12-year-old recipient lung

[2] OPTN data as of October 2022.

transplants. A member also noted that most exception requests would likely be approved. A member noted drawing the line at 12 years old is tricky because the composite allocation score (CAS) does not distinguish them. A member noted the World Health Organization (WHO) considers an individual pediatric from 0-17 years old. Members agreed all reviewers should be familiar enough with pediatric policy that it should be okay if the reviewers are only adult specialists. The system will assign nine reviewers to each case, and pediatric reviewers would be given priority for pediatric cases. Changing the system to have only five reviewers for pediatric cases would be out of scope for this implementation and would have to be addressed in a new project. The Committee agreed to move to 13 transplant programs represented on the review board to incorporate a fourth pediatric reviewer, and to require transplant programs to have completed at least one transplant for a candidate under the age of 12 in the last five years in order to qualify as a pediatric reviewer

UNOS staff noted that once cases are closed, comments will be able to be viewed by all reviewers. There are 11 programs with an active pediatric candidate. There was one pediatric exception requested for under 12 years of age in the last two years. Staff noted that setting up a separate review board, reducing the number of voters on pediatric cases, and limiting pediatric cases for ages 0-12 would need to be a separate project. Setting a requirement of who qualifies to review these cases is something that could be included in this proposal.

Transplant Program Representation

The Chair asked for follow-up on whether the active cohort of the Review Board can be broken down by size and geography to ensure proper representation between programs. She also stated that small centers may not have the experience for the exceptions that are requested.

Chair Role

The Committee discussed whether the Chair should be a voting member. The immediate pastchair of the Committee and future chair of the Review Board explained that the intention of having the Review Board chair as a non-voting member was to ensure that there was a connection between the Committee and the Review Board, and that the Review Board chair could bring policy ideas to the Committee that were frequently submitted as exception requests. She noted this guidance may be retrospective, since from an IT standpoint this cannot happen before the vote, but it would be helpful to learn from these cases and identify themes. Members agreed that having this guidance from the Review Board chair would be helpful and may not be appropriate if the Review Board chair was a voting member. Members noted that it is a key learning point to review what their peers are saying about these cases to pass onto the lung community, and this will help programs know when submitting an exception is appropriate.

Members asked how this is done for liver. UNOS staff responded that the current chair is a voting member but is not required to be a voting member. The National Liver Review Board chair reviews redacted narratives to come up with guidance, policy, and templates for adequate exception requests with the OPTN Liver and Intestine Transplantation Committee.

Multiple Listings

Members also stated that exceptions should travel with candidates from center to center, and the Review Board will have to see to that. SRTR staff stated that the system is inadequate in assessing a candidate's score at different centers, but the system is a national system and should be consistent. UNOS staff responded that the values a candidate receives are specific to that center, and it is not up to the OPTN to dictate which values hold precedent over others. Members stated that there is no mechanism in place for this currently, so that would need to be addressed via a separate project.

Appeals to the Committee

Members suggested that appeals to the Committee need to be reviewed very quickly and agreed it is too nebulous to state that these will need review before the next committee meeting. Members discussed how many people need to meet to review appeals and agreed that five members is adequate for review of appeals. A member stated there should be a requirement that these reviewers have previously adjudicated a request before. The Chair noted that the subcommittee that would be reviewing requests would include about 16 physicians and surgeons from the Committee, but there is no guarantee that they would have all served on the Review Board before. Members noted this will be discussed through email or teleconference, and exception history can be seen for that candidate. Members agreed open communication on votes should be discussed via teleconference when it comes to appeals. All members of the subcommittee will be contacted to get as many reviewers as possible, but the minimum will be set to five. Members agreed to update policy to require the Committee to review appeals within 14 days, but in practice the Committee will aim to review appeals within 7 days or less. Members asked if appeals should be approved if a minimum of five reviewers cannot convene within 14 days. Members agreed that this chance is small, but the Committee will give these centers the benefit of the doubt because of the level of work involved to appeal. The Chair stated many are not even aware of how this system works.

Members agreed that giving guidance on how to request pediatric priority one is warranted, and additional educational offerings should be made available.

2. VOTE: Do you support sending Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution to the Board of Directors in December 2022?

UNOS staff reviewed final policy language with the Committee and asked the Committee if they vote to bring this proposal to the OPTN Board of Directors in December 2022.

Summary of discussion:

The Committee members unanimously voted that they support sending this proposal to the OPTN Board of Directors in December 2022 (16-yes, 0-no, 0-abstain).

3. Review and discuss public comment feedback on Update Data Collection for Lung Mortality Models

UNOS staff explained that the proposal includes data removals, data revisions, and data additions. It would not change the mortality models for the allocation score at this time. This proposal would assign values for candidates on extracorporeal membrane oxygenation (ECMO) or high flow nasal cannula (HFNC) to be used in calculating allocation score. This proposal would be implemented after continuous distribution, and SRTR estimates it would require two years of new data collection to consider updates to mortality models.

'Percent Predicted Forced Vital Capacity,' 'Post Bronchodilator Actual FEV,' 'Pre-Bronchodilator Percent Predicted FEV,' 'Post Pre-Bronchodilator Percent Predicted FEV,' 'Requires Supplemental Oxygen: How was the value obtained' are all data fields that were identified for removal. Revisions included:

- Lung Diagnosis Code: Add Combined Pulmonary Fibrosis and Emphysema
- Diabetes: Change "insulin dependent" to "treated with insulin"
- Assisted Ventilation: Add hospitalization status for intermittent mechanical
- Requires Supplemental Oxygen: Allow more detailed data entry by oxygen delivery device and candidate activity level
- Six Minute Walk Distance: Change placement in system and clarify definition

Data additions include NYHA Functional Classification (PH only), BNP NT-proBNP (PH only), pericardial effusion (PH only), recurrent pneumothoraces, bronchopleural fistula, massive hemoptysis in the last year, exacerbation in the last year, microbiology within last year and/or ever, prior lung surgery, prior cardiac surgery, pleurodesis, diffusing capacity of the lungs for carbon monoxide (serial data collection), mean right arterial pressure, and pulmonary vascular resistance.

Feedback highlighted the data burden of this proposal, including a comment that data burden could impact data quality. However, many comments emphasized the value of the proposed data additions. There were requests to the Committee to continue to remove data fields that do not factor into allocation or do not add value. There was limited feedback that suggested leveraging electronic health records (EHRs) to work with EHR vendors for retrospective data collection and adopt APIs. Societies asked for education on the new data collection fields and revisions to transplant programs.

Feedback from public comment requested data collection be required, but that the data fields be deemed important before requiring it.

Regarding exacerbations, feedback included:

- Add definition for candidates with pulmonary arterial hypertension – recurrent hospital admissions due to right heart failure
- Include need for hospitalization in definitions for chronic obstructive pulmonary disease (COPD) & cystic fibrosis (CF)
- Collect number of exacerbations that required hospitalization in addition to total number of exacerbations
- Definitions should be more detailed, less subjective, and evidence-based
- Add “treatment required” to all definitions to avoid gaming

Regarding microbiology, feedback included:

- Add *Lomentospora* under reportable multi-drug resistant (MDR) organisms due to a change in nomenclature
- Concern about the organisms selected, noting that as far as fungal infections, there are not specific data to favor the organisms listed
- Consider distinguishing between MDR and Pan-R gram negative bacteria
- Modify list to reflect groups of organisms so that it is less specific

Regarding assisted ventilation, feedback included:

- Patients who have been on ECMO for weeks have worse post-transplant outcomes than someone who is only on ECMO for a few days
- Choice not to capture ECMO settings is reasonable
- Use of VA/VV ECMO may reflect center level practices in addition to patient severity

Regarding supplemental oxygen, feedback included:

- Define the machine being used for supplemental oxygen since the fraction of inspired oxygen (FiO2) varies based on the machine being used
- Clarify how oxygen delivery device will impact the lung allocation score and composite allocation score (LAS/CAS), especially for individuals with oxygen requirements greater than 26.3 L/min
- Recommend using FiO2 and not L/min to promote standardization
- For HFNC - calculate the true oxygen flow rate by multiplying the flow rate and the calculated flow rate based on FiO2, rather than using the higher value of the two

Regarding diffusing capacity for carbon monoxide, feedback included:

- Diffusing capacity for carbon monoxide (DLCO) data could be difficult to use if not corrected for hemoglobin, since the data could have a lot of variability that would not necessarily reflect severity
- Important to collect DLCO values corrected for hemoglobin as well as for alveolar volume

Regarding prior lung and cardiac surgery, feedback included:

- Video-assisted thoracoscopic surgery (VATS) is a technique used for surgery and not a type of operation itself
- Data collection should be modified to whether each of the surgeries performed was done VATS or open (i.e., VATS lobectomy vs. open lobectomy, VATS wedge resection vs. open wedge resection, etc.

Feedback regarding the data additions included a request to require more frequent updates to clinical data for patients with higher allocation scores since they are a very different population from the patients with lower allocation scores, a request to include simple measures of frailty that may predict waiting list mortality post-transplant mortality, a request to include immunodeficiency, such as hypogammaglobulinemia, or if a patient has undergone an allogenic stem cell transplant prior, as the community is seeing more interstitial lung disease (ILD) related transplants regarding mixed connective tissue disease or connective tissue disease, and a request to include elements to assess pre- and post-mortality for elderly lung candidates, including donor characteristics.

Additionally, there was a request to remove age as a determinant for transplant from the spouse of a candidate who was denied evaluation for lung transplant.

The Committee considered the following points regarding feedback on alternate data sources:

- Public comments recommended exploring retrospective data collection or partnering with electronic health record (EHR) vendors
    - Concern is that resources used for data collection could be used towards obtaining data elsewhere
- Previous OPTN effort for retrospective data collection was resource intensive – trained staff to look at medical records
- While project includes updating OPTN Waiting List application programming interfaces (APIs) to facilitate data entry, challenges remain
    - Transplant hospitals/EHR vendors would also need to make updates for full functionality
    - APIs do not “pull” data – transplant hospitals must “push” data
    - Setting up infrastructure to facilitate additional data exchange from EHRs would take time

Therefore, the Committee discussed two paths forward:

- Submit modified proposal with limited data fields
    - For fiscal purposes and cost reduction, consider collecting some data fields on Transplant Candidate Registration form (TCR) instead of OPTN Waiting List
- (2) Request SRTR to evaluate if CF and pulmonary hypertension (PH) data points obtained from REVEAL and CF Foundation Registries could be incorporated into mortality models
    - Could result in adding variables to the models more quickly than waiting for data collection via Waiting List
    - Less burden on transplant programs

The OPTN will continue to evaluate alternate options for collecting data for the purpose of developing allocation policies.

The Chair concluded that this approach would allow the OPTN to collect DLCO in OPTN Waiting List; collect New York Heart Association (NYHA) functional classification, BNP NT-proBNP, pericardial effusion, mean right atrial pressure, pulmonary vascular resistance, microbiology, massive hemoptysis, and exacerbation in OPTN Waiting List and evaluate alternative data; and remove prior lung surgery, pleurodesis, prior cardiac surgery, recurrent pneumothorax, and bronchopleural fistula from the data additions in OPTN Waiting List.

UNOS staff provided an overview of the changes to data collection of supplemental oxygen. She explained that 'at night' will change to 'with sleep' and supplemental oxygen needs at those different activity levels will be able to be entered separately. Values up to 100 liters per minute will be able to be entered and device selection options will be added.

Data Summary:

The proposal was supported across regions. Three representatives in regions 8 and 10 indicated opposition. The proposal was opposed by one organ procurement organization (OPO) member and three transplant hospitals but was generally supported by members.

Summary of discussion:

An SRTR representative clarified that the action requested of SRTR is to look at estimates from papers and registries to see how the models would be impacted for these populations in terms of whether this would make an impact in better capturing waitlist mortality in the allocation algorithm. The Chair stated that is correct. SRTR agreed to examine the CF and PH data points, but they do not have a time frame on when this will be done. SRTR staff stated this would be completed a few weeks after December, and they cannot commit to whether it is doable. The first step would be identifying the methodology and then determining if adding these variables to the model would determine better waitlist mortality.

SRTR staff noted DLCO has a combined pulmonary fibrosis emphysema cohort that is being missed completely. She explained that there are several mixed diseases that oxygen is the only field able to measure them, so DLCO will be an additional way to do that. A member suggested the addition of severe exertional hypoxemia. SRTR staff explained this could be captured under oxygen with exercise as a data addition.

The Chair summarized the criteria that would be removed from the proposal (prior lung surgery, pleurodesis, prior cardiac surgery, recurrent pneumothorax, and bronchopleural fistula) and explained this is because data will not be available for years due to the small number of cases that fall into these categories. She explained that centers can apply for an exception for these patients. SRTR staff explained these fields are so nuanced and their incorporation into a big registry will not be helpful. She noted the SRTR data for these fields is non-specific and full of nonrandom missingness. A member asked if this data is captured when centers apply for exceptions to see what is frequently requested as an exception. A member responded that because the OPTN is shifting to an allocation model that includes a 1:1 ratio of expected waiting list survival to post-transplant survival instead of waitlist urgency receiving so much weight, it makes sense to collect information on why candidates are dying on the OPTN Waiting List.

SRTR noted that prior cardiac surgery does not show up on center reports. She argued the surgical comorbidities affect surgery and post-transplant outcomes, which are not available in PSRs. She emphasized the frequency is so low. UNOS staff explained prior cardiac surgery is collected on the TCR

and the Transplant Recipient Registration form (TRR), and prior lung surgery is captured only on the TRR. She offered updating these forms instead of putting these fields in the OPTN Waiting List. Committee members agreed to collect prior surgery information only on the TCR and to update the data collection on the TCR with the options developed as part of this proposal.

A member stated the Committee should gather data first to justify this data collection because the current optics are not sufficient. She argued the Committee needs to substantiate that this data will make a difference. She noted program staffing is very differential and this could be a huge barrier for lower staffed programs. The immediate past chair stated that coordinators need to know exactly which factors should be entered for waitlist mortality and post-transplant survival, and they answer every question currently. She explained that trying to get the data retrospectively is a huge endeavor that costs a lot of money. Hospitals would need to spend thousands of dollars to get APIs in place. She cautioned the Committee from continuing to push this off. A member suggested getting an API database collection at seven large centers or getting the data from SRTR to show the community. She stated microbiology is not feasible for every center to input. The Chair stated there are a lot of variables and data points that are coordinator burden, and the Committee is aware of that, but completing a pilot study is not feasible. She noted there is not a single center that has an API in use right now.

SRTR staff stated there is scientific evidence that these variables matter. She explained that SRTR could possibly look at the incorporation of these variables into OPTN Waiting List and examine the effect estimates to see the impact. SRTR staff explained this will take a few weeks to determine if feasible and examine the trajectory of the disease, then several months to examine the impact and feasibility. UNOS staff explained that the final product will need to be delivered to the OPTN Board of Directors in the middle of November. The Vice Chair suggested going to the Board and stating that feasibility is still being assessed by SRTR. A member stated it is better to bring this to the June Board of Directors meeting, so that feasibility is determined. The Vice Chair noted the data was determined to be important through the clinical literature.

A member stated we are missing a chunk of ILD and COPD patients by not collecting this data for all lung candidates. He noted exacerbation data needs to be captured. Members agreed that the Committee should push forward to collect the data because the literature shows this. SRTR said that capturing variables that define diseases is most important, and that is what the Committee has done with DLCO. A member noted that the goal is to allocate organs to those who are dying but have not crashed yet, so outcomes improve. Ambulatory patients that have a change in their DCLO will be prioritized better instead of waiting until they are too hypoxic to complete a DLCO anymore. Members stated a delta DLCO will not be a marker of disease since it is not completed when a patient is very sick, and it will not continue to be checked. A member stated this needs to be in OPTN Waiting List to encourage serial DLCOs. The Chair explained this will be difficult because patients will not be able to tolerate it as they get sicker, and transplant centers do not have the staff. Another member emphasized putting in place the easiest options for centers and noted gathering extensive data on DLCO will be challenging. SRTR stated one DLCO is enough since candidates are not on the OPTN Waiting List that long. The immediate past chair explained that for spirometry there are options to fill in pre-listing data from six months prior, so this would be an option for DLCO too.

A member asked about the distinction between HFNC and heated high flow and noted this needs to be better defined. The Chair and Ex-officio stated that could be defined in the help documentation. The member responded that for high flow nasal cannula both numbers must be entered, and this should cause coordinators to properly enter FiO2 and liter flow. The Chair stated after analyzing questions the Committee receives then this can be incorporated into help documentation.

UNOS staff explained that prior lung surgery is currently collected on the TRR, and it could be updated to be on the TCR to reflect what was originally discussed by the Updating Mortality Models Subcommittee. She also noted that prior cardiac surgery could be changed to sternotomy, and members agreed. A member stated clarification should be provided that the Committee does not want to capture percutaneous valves. A member stated the Committee should evaluate whether these variables will affect initial registry. The immediate past chair asked if this data is worth collecting at all. A member stated capturing VATS seems like it may be important. The Vice Chair stated the Committee may want to re-add the surgical approach options into this data collection. The immediate past chair stated it will be difficult for this to be understood on a coordinator level. Members agreed the incision/approach type does not need to be added.

A member stated it will be difficult to develop a rule on post-transplant outcomes with these patients because it will not be consistent. A member stated a study he conducted with SRTR data showed there were 300 coronary artery bypass graft (CABG) out of 13,000 lung transplants that had worst post-transplant survivals. He guesses 30 patients had prior cardiac surgery. Members noted the goal of this data collection is to better inform allocation and assess what affects post-transplant outcomes. A member asked if this will be incorporated into the CAS. The Vice Chair stated if it impacts outcomes and survival, it will need to be included.

4. Finalize Mortality Models Proposal

Policy 21.2.A *Values Used in the Calculation of Lung Waiting List Survival* will be changed to reflect whether values are expired to clarify what happens when values expire for candidates on ECMO. The former OPTN Thoracic Transplantation Committee recommended that ECMO candidates should be reported as being on continuous mechanical ventilation and getting 100% supplemental oxygen. Transplant programs will now be able to enter whether their patients are on ECMO, and the hope is that they accurately report their supplemental oxygen usage. This needs to be done so that these patients are not losing points by reporting accurate data. If these fields are current, they will get their maximum points for supplemental oxygen, or 26.33 l/min. If a candidate is on ECMO and fields are reported within 28 days, they will receive the maximum score. If a candidate has expired ECMO, they will receive the points for their supplemental oxygen reported at rest. If a candidate's supplemental oxygen field is expired, the program has not kept up with the policy requirements, so the candidate will get the least beneficial value. If ECMO and supplemental oxygen fields are both expired, the candidate will receive no benefit.

The OPTN Ad Hoc Disease Transmission Advisory Committee recommended a definition of multi-drug resistant organisms (MDRO) and the addition of lomentospora, which is a scedosporium that was reclassified. They suggested distinguishing between MDR and pan-resistant. The immediate past chair noted this is not consistent throughout labs and the Committee opted not to adopt this change.

Date fields will be added for the data collection additions. Exacerbation, hemoptysis, and microbiology will be updated from "in the last year" which refers to from date of registration. Subsequent entry will be based on last evaluation date. Data elements that are clinical values would be test dates, and the rest of these elements will be date of evaluation (referring to the date of the clinic visit).

DLCO public comment feedback stated DLCO data could be difficult to use if not corrected for hemoglobin, as well as alveolar volume.

Feedback on definitions for exacerbations included:

- Add definition for pulmonary arterial hypertension
- Include hospitalizations in definitions for COPD and CF
- Collect number of exacerbations that required hospitalizations and total number of exacerbations
- Make definitions more detailed, less subjective, and evidence-based
- Add something to the definition such as “treatment required” to avoid gaming

Summary of discussion:

A member stated there is a difference between patients on ECMO for hypoxemia or hypercapnia. She recommended collecting information on the ventilatory status. The immediate past chair stated they could be listed under ECMO and mechanically ventilated.

Members noted that no information on ECMO settings will be collected. The center will need to update ECMO and supplemental oxygen regularly. A member asked about the situation when a candidate is on ECMO and room air so no supplemental oxygen is used, and that field will not be updated. The 28-day report will require this field is updated regardless. Members noted the potential for the score to drop will prompt programs to evaluate this.

A member stated the addition of dates may not be necessary and will be difficult to collect. She stated dates of episodes of massive hemoptysis is not something she knows for all her patients. The Ex-officio explained that updating from the last data entry is what is required. She emphasized this is not the date the event occurred, but rather the date of the evaluation.

The Chair stated DLCO values must be corrected for hemoglobin. A member stated that hemoglobin values can sometimes be obtained on different days. Members stated obtaining on the same day is only possible when getting arterial blood gases (ABGs) the same day as well. SRTR staff asked if it matters what the corrected score is because corrected values affect the lung disease but not the measure of the DLCO. Members agreed to go with noncorrected values since there is no standardized approach to this. A member stated DLCOs are not valuable for pediatric candidates because they are gathered once if they can even be gathered.

The Committee discussed the feedback on exacerbations. The Chair stated that PH readmission is not an exacerbation of their PH, but rather a progression of their disease. The immediate past chair stated hospitalizations require different thresholds and are not standardized. Members agreed definitions are detailed and treatment required is listed in several of the definitions.

The Committee discussed how exacerbations should be reported for candidates with multiple lung disease diagnoses. The Chair stated guidance should be that the definition for each candidate should reflect what they are listed as. A member stated this will be an issue with CFPE. A member argued candidates always exhibit ILD exacerbations or worsening of their PH, so this should not be an issue. Members agreed the definitions are adequate as is.

5. VOTE: Do you support sending Update Data Collection for Lung Mortality Models to the Board of Directors in December 2022?

UNOS staff reviewed final policy language with the Committee and asked the Committee if they vote to bring this proposal to the OPTN Board of Directors in December 2022.

Summary of discussion:

The Committee members unanimously voted that they support sending this proposal to the OPTN Board of Directors in December 2022 (16-yes, 0-no, 0-abstain).

6. Donation After Circulatory Death (DCD) Lung Transplant Collaborative

UNOS staff explained their goal is to increase the number of DCD lung transplants. DCD transplanted lungs have favorable outcomes in recipients. Increasing the acceptance and utilization of these organs may positively impact the number of lung transplants. This project includes the DCD Procurement Collaborative work with OPOs and is of interest to members of the transplant community. The goal is to engage at least 15 programs and deploy from November 2022 to July 2023. Forms for interest will need to be submitted by October 28, 2022.

UNOS staff have completed four Practice Model Organization visits, drafted an Improvement Guide (IG), and refined deployment. They are currently solicitating participant interest and preparing orientation, website, resources, etc.

The project will be rolled out in two improvement phases. From December 2022 to March 2022, the project will optimize internal program processes and patient care practices. This will include internal communication and multi-disciplinary practices, organ offer review processes, and candidate listing practices and care coordination. From April 2023 to July 2023, the project will strengthen relationships with OPOs. This will include communication of donor assessment and ongoing clinical evaluation, recovery and logistical needs, and pre- and post-recovery huddles.

The benefits of the collaborative include:

- Focused time and space to improve
- Structured engagement
- Discussions of challenges and successes
- Shared resources and ideas
- Common goal but not prescriptive

Summary of discussion:

The Chair thanked UNOS staff for the presentation. She stated that the extension of the deadline date is helpful. She encouraged members to consider participating. She requested the form for submission be done in a different format. The Vice Chair asked how many programs have expressed interest. UNOS staff stated they have received eight forms from programs but are anticipating more. The Chair agreed.

The Chair asked if UNOS staff suggests working with an OPO in the transplant program's region or outside of their region. UNOS staff responded that everyone has requested to work with their local OPOs, but it does not matter. The Chair encouraged others to branch out from their local OPO. UNOS staff said the deadline is not a hard deadline, so members should reach out if they need more time.

A member stated the timeline may be too fast to develop and implement an intervention and then monitor and see changes. UNOS staff responded this is a continuous struggle and one of their goals is to connect with people quickly who plan to move forward with this project. She stated that once UNOS staff step back, implementation and monitoring continue.

7. Heart ABOI Project Update

The purpose of this project is to update policy to align with current research findings relating to ABOi pediatric heart transplant to increase the donor pool and reduce wait time. The OPTN Heart Transplantation Committee proposes modifications to Policy 6.6.B: *Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts.* This will safely expand access to donor hearts for candidates less than 18 years old, reduce the volume of discarded donor hearts, and improve data collection and reports related to ABOi listings and transplantation. The proposal has been expanded to include pediatric heart-lung and lung candidates.

The changes to *Policy 10.4.A Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs* would include:

- Increasing eligibility age to "registered prior to turning 18 years old"
- Removing "waiting list survival score of at least 1.9073" which reflects pediatric priority 1 for lung
- Removing "registered prior to turning two years old" and survival score

The Committee noted pediatric ABOi lung transplants are rare and supported amending lung policy as part of this proposal.

The OPTN Heart Transplantation Committee unanimously voted to approve these changes to their proposal. They will include feedback questions about appropriateness on increasing eligibility age for access to ABOi lungs in their proposal.

Summary of discussion:

A member stated since current OPTN policy prohibits ABOi transplants older than the age of 2, so they have not thought about doing so. He flagged that it is an issue when a child who received an ABOi transplant needs to be listed for a retransplant and are listed using their actual blood type instead of the incompatible blood type for hearts. Centers will likely not change things internally, so there is no issue with this.

8. Demonstration: Phase 1 implementation for continuous distribution of lungs

UNOS staff explained that continuous distribution will be rolled out in two phases. Phase one will include prior living donor data collection, HFNC data collection, and the lung CAS 28-day report. Prior living donor data collection will be implemented with phase one for lung and heart-lung data collection prior to allocation changes in phase two. This will be implemented with a default "no" response for all lung and heart-lung candidates. It requires submission of information required in *Policy 10.1.D.2 Prior Living Donors* to the Organ Center. In each lung candidate listing, the transplant community will not have permission to edit the prior living donor field but will be able to see the response for the candidate on the listing and edit pages. UNOS staff gave an overview on how to access the form in the OPTN Computer System.

HFNC data collection will be implemented with phase one for lung and heart-lung data collection prior to allocation change in phase two. In phase two, candidates on HFNC will require more frequent updates. A new supplemental oxygen child field will be available. All candidates requiring supplemental oxygen at rest, with exercise, or at night require a response. This will be implemented as blank for lung and heart-lung candidates, then requires update of the appropriate response. When a candidate requires supplemental oxygen, the additional fields for response include HFNC, amount (L/min or percent), and how was the value obtained.

A new report was created to support compliance with the new 28-day reporting policy. This includes a report to support the transition period for the new HFNC field.

Implementation of continuous distribution is set for the end of January 2023.

UNOS staff gave an overview of the Lung CAS Report Training Version. UNOS staff gave an overview of the summary statistics for the CAS.

Summary of discussion:

The Chair asked if percent and L/min need to be entered for HFNC. A member noted that HFNC and heated high flow are different. A member stated the value that gives the patient the most benefit will be

taken. The member responded that she had previously done her own calculation to be more accurate. UNOS staff stated the intent here is to align with the policy requirement that people on high flow need to update their supplemental oxygen assisted ventilation more frequently. The immediate past chair noted that nothing different with oxygen will be captured until the potential implementation of the Updating Mortality Models proposal. The Chair recommended putting in the highest value will be read from the device.

A member stated sometimes someone can be on FiO2 and liter flow, but if both of those numbers are entered it looks like someone is on heated high flow when they are not. The Committee agreed to put this into help documentation on what to enter. The member stated the form should ask about supplemental oxygen, ask the liters, and then ask if they are on heated high flow. The immediate past chair emphasized the system will choose the value that is most beneficial. The member stated it should be changed to 'On heated high flow nasal cannula?' Members stated high flow versus heated high flow must be defined. Staff offered to define high flow nasal cannula in forthcoming communications to lung transplant programs.

The Chair noted there is still a lot of uncertainty throughout the lung community, specifically from medical directors on the changes coming with continuous distribution. She suggested targeting medical directors separately and providing education for coordinators. She stated it may be helpful to go through a patient example with coordinators in webinar form. She vocalized concern over the timeline especially because it falls shortly after the holidays. She suggested March of 2023.

A member stated administrators do training for the coordinators, and they should be targeted. A member emphasized the helpfulness of the webinar and encouraged coordinator-specific webinars. Outreach to lung programs will start soon. The Chair cautioned that medical directors should be targeted since they are responsible for educating everyone. Another member stated the transplant program director will be helpful as well. Members emphasized providing real patient examples and helping centers maximize opportunities for their patients. In the OPTN learning management system, UNOS Connect, there are four educational opportunities, and 'scoring and exceptions' has all the patient examples. The Chair stated this should be done through a webinar. A member asked if regional meetings could take place, and UNOS staff suggested regional town halls.

UNOS staff noted there are few changes to the interface. A member asked about providing a CAS calculator prior to implementation. UNOS staff stated it is risky to implement the calculator before implementation and to maintain two allocation calculators. Members suggested adding a simulator. A member noted that when examining the difference in scores for his candidates for their lung allocation score (LAS) versus CAS it raised questions due to most of his candidates receiving scores in the twenties. UNOS staff explained medical urgency and post-transplant is a candidate's entire score currently, but that is now only 50 points, or half of the score, in the CAS. She explained that getting the full points for any attribute is not possible. A member stated she is not comfortable with all the other biological disadvantages.

UNOS staff stated that the new CPRA calculation will be implemented November 30, 2022. A release on pre- and post- implementation CPRA scores will be available the week of 11/2/22. SRTR staff asked if it is possible to give projected waitlist mortality and projected post-transplant survival numbers. UNOS staff explained that is already broken out in the lung CAS report. Members vocalized concern over the spread of candidates' scores. The Ex-officio noted the waitlist mortality is a very small number due to the shape of the curve. UNOS staff explained the 29 pediatric registrations (as of September 16, 2022) will be in the top spots. Members reemphasized the need for an interactive calculator before implementation to help members understand what is driving these changes.

Members noted that these resources are difficult to find. UNOS staff stated a crosswalk will become available for the community. The Committee reemphasized their suggestion to push back implementation.

9. Discuss NASEM Recommendations

UNOS staff gave an overview of the National Academies of Sciences, Engineering, and Medicine (NASEM) Report, stating, the NASEM Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution issued a report "Realizing the Promise of Equity in the Organ Transplantation System" in February 2022.[3] The OPTN Board of Directors responded to the NASEM report in April 2022, and the NASEM committee leadership presented the report's recommendations to the Board of Directors in June 2022.

The recommendations fell into the categories of improving equity, using more donated organs, and improving the system and system performance. UNOS staff explained how the OPTN has worked to incorporate these recommendations.

Summary of discussion:

SRTR staff asked what the OPTN is doing to better incorporate socioeconomic position (SEP) into the allocation models. UNOS staff explained data with a variety of social determinants of health was acquired to get meaningful inferences for incorporation, and this fiscal year will involve work with OPTN committees to see how to use that data. There is currently only kidney data, but UNOS staff is working to acquire lung data for the Committee. The OPTN Liver and Intestine Transplantation Committee has also discussed incorporating social determinants of health into continuous distribution.

The immediate past chair stated that the system is very weighted towards kidney in terms of approaches for improving organ offer acceptance, but for lung it will be hard to incorporate computerized tomography (CT) reports and bronchoscopy reports into data. She stated there is a lot of work to be done around standardization of evaluation prior to making an offer because that is currently extremely variable amongst OPOs. She struggles to think about optimizing use of organs because center turn down for lungs is so complicated. The community currently uses vague refusal codes because of this.

A member stated collecting information on compliance will better allocation. She suggested collecting data on vertical and horizontal heights because it is not always appropriate to base biological disadvantages on only height. The immediate past chair noted that the curve for height differs by disease process. The member stated collecting this donor information can be quantifiable.

Members stated it is difficult to collect data on organs that should not be discarded, but current work is mostly kidney focused. They emphasized that this is very subjective because centers make decisions to avoid compromising long term outcomes. A member noted DCDs are an opportunity, but Spain and Australia have different legal practices that make it easier to pursue DCD organs. In the U.S., there is the fear of poor outcomes beyond the cost factors. A member suggested incentivizing programs to do DCD transplants.

Members discussed patient access to transplant. A member stated when a patient is denied from two centers but goes to a third center, that patient can afford it and has good health literacy. He suggested there is a disincentive to take those high-risk patients locally, especially at smaller centers. A member

[3] "Realizing the Promise of Equity in the Organ Transplantation System," National Academies of Science, Engineering, and Medicine, accessed November 19, 2022, https://www.nationalacademies.org/our-work/a-fairer-and-more-equitable-cost-effective-and-transparent-system-of-donor-organ-procurement-allocation-and-distribution.

stated distance and time affects whether a DCD donor will be considered. Members agreed that having a team and additional resources makes this possible. A member stated those who do DCD transplants have physicians do the recovery and this allows transplant surgeons to stay at their centers, but sometimes they are still waiting two hours for the patient to die.

A member stated improvement is needed in the efficiency process because donor offers are made without CT scans. She recommended providing a walk-through list of requirements that must be completed before making offers. A penalty needs to be enforced when this list is not completed.

The Chair stated there is such variation on how an OPO will handle a DCD, and that needs to be standardized. The Chair stated procurement teams need to be certified. Members noted local OPOs must be ACIN certified.

Next steps:

The Policy Oversight Committee will prioritize project ideas related to the NASEM report.

10. Next Steps and Closing Comments

The Chair thanked members for attending and participating.

Summary of discussion:

There was no further discussion by the Committee.

Upcoming Meetings

- November 17, 5pm-6pm EST, teleconference

Attendance

- **Committee Members**
  - Marie Budev
  - Erika Lease
  - Brian Armstrong
  - Dennis Lyu
  - Edward Cantu
  - Errol Bush
  - John Reynolds
  - Julia Klesney-Tait
  - Karen Lord
  - Lara Schaheen
  - Marc Schecter
  - Matthew Hartwig
  - Nirmal Sharma
  - Soma Jyothula
  - Scott Scheinin
  - Stephen Huddleston
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - David Schladt
  - Katherine Audette
  - Maryam Valapour
- **UNOS Staff**
  - Kaitlin Swanner
  - Taylor Livelli
  - Holly Sobczack
  - James Alcorn
  - Krissy Laurie
  - Nelson Marrero
  - Rachel Hippchen
  - Sara Rose Wells
  - Tatenda Mupfudze
  - Terry Cullen
  - Susan Tlusty