PUBLIC COMMENT NOTICE

To:	OPTN/UNOS members and other interested persons
From:	Douglas A. Heiney, Director Department of Membership Services and Policy Development
Re:	OPTN/UNOS policy proposal for public comment
Date:	March 25, 2004

Attached for your consideration is a policy proposal regarding modifications to the current lung allocation system that is being issued for public comment. This proposal addresses issues considered during recent meetings of the Thoracic Organ Transplantation Committee.

Following public comment and reconsideration by the appropriate committee(s), this proposal may be offered for consideration by the committee(s) to the OPTN/UNOS Board of Directors at its June 24-25, 2004, meeting. Please mail, fax, or email your comments on this proposal to UNOS by May 9, 2004.

UNOS appreciates receiving your response to these important issues.

Attachment

Background

The United Network for Organ Sharing (UNOS) is a tax-exempt medical, scientific, and educational organization. On October 1, 2000, UNOS received a federal contract to continue operation of the national Organ Procurement and Transplantation Network (OPTN) and development of an equitable, scientific and medically-sound organ allocation system. The OPTN is charged with developing by-laws and policies that maximize utilization of organs donated for transplantation, assuring the quality of care for transplant patients, and addressing other complex medical issues related to organ transplantation in the United States. All by-laws and policies receive broad input from numerous constituencies including transplant patients, patient and donor families, the OPTN membership, and concerned individuals and organizations throughout the United States.

By-Laws and policies are adopted by the OPTN/UNOS Board of Directors pursuant to the UNOS contract with the United States Department of Health and Human Services (DHHS) and after circulation and discussion among organ transplant professionals and patient representatives. These by-laws and policies have been submitted to the Secretary of DHHS for review and are considered voluntary guidance to OPTN members until approved as OPTN rules and requirements by the Secretary of DHHS. UNOS is responsible for updating these by-laws and policies and for monitoring compliance by OPTN members. Instances of noncompliance with by-laws and policies may lead to disciplinary action, including, for example, designation as a member-not-in-good-standing by the Board of Directors. In addition, instances of non-compliance are reported to the Secretary of DHHS.

The proposal that follows addresses issues considered during recent meetings of the Thoracic Organ Transplantation Committee. Following public comment and reconsideration by the appropriate committee (s), the proposal in this document may be offered for consideration by the OPTN/UNOS Board of Directors at its June 24-25, 2004, meeting in Minneapolis, Minnesota.

This policy proposal is also available for review on the OPTN and UNOS Internet Web sites at www.optn.org and www.unos.org. Comments on this proposal may be submitted electronically at these sites.

Circulation of Notice

UNOS maintains a public comment distribution list for policy and by-law proposals. To be included on the distribution list, submit a written request to UNOS at the address below. All policy and by-law proposals issued for public comment are mailed or delivered by electronic notice (at the recipient's option) to the distribution list. UNOS typically accepts comments from the public for at least 45 days after publication of the proposals and public hearings on the proposals are arranged if warranted.

Comment Deadline

The proposal in this document is being issued for public comment on March 25, 2004. To be considered, comments must be submitted in writing, or by completing the enclosed Public Comment Response Form, and sent to the UNOS contact person at the following address by May 9, 2004:

United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218
FAX (804) 782-4896

UNOS Contact Persons

Inquiries regarding the policy proposal in this document should be made to the appropriate UNOS Regional Administrator at (804) 782-4800. The UNOS Regional Administrators are as follows:

Fred Geiger (geigerfr@unos.org)

Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 4 - Oklahoma, Texas
Region 9 - New York, Western Vermont

Elizabeth Gans (gansel@unos.org)

Region 2 - Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 5 - Arizona, California, Nevada, New Mexico, Utah
Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington

Clifton McClenney (mcclence@unos.org)

Region 3 - Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 10 - Indiana, Michigan, Ohio
Region 11 - Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Allocation of Lungs: Proposed Amended OPTN/UNOS Policy 3.7.6 (Status of Patients Awaiting Lung Transplantation), Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates), Policy 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF)), and Policy 3.7.11 (Allocation of Lungs)

1. Summary

The OPTN/UNOS Thoracic Organ Transplantation Committee proposes a new system for allocating lungs that uses lung transplant candidates' waitlist medical urgency and transplant benefit to determine priority for lung offers. The proposed system would assign priority to lung candidates who are at higher risk of death if they do not receive a transplant (waitlist urgency) and who are likely to receive a greater benefit of longer lifetime with a transplant as compared to without a transplant (transplant benefit). This proposal would replace the current system that assigns priority to lung transplant candidates based solely on the amount of time they have accrued on the lung waitlist. The Committee predicts that these changes to the lung allocation system would direct lungs to those candidates who are most urgently in need of a lung transplant and who are expected to receive the greatest survival benefit from the transplant. The proposal includes provisions for updating transplant candidates' clinical status, regular periodic review and improvement of the algorithm, and assigned allocation priority for pediatric candidates.

A. Policy Goals

The proposed lung allocation system is intended to accomplish the following goals:

1) Reduce the number of deaths on the lung transplant waiting list.

2) Increase transplant benefit for candidates who receive a lung transplant.

3) Ensure efficient and equitable allocation of lungs to active transplant candidates.

B. Features of the Current Proposal

The proposed lung allocation system is a complex system, designed to take into account many factors that affect the severity of transplant candidates' illnesses and the likelihood of their prolonged survival following the transplant operation.

The proposed system will assign priority for donor lungs based on each candidate's **risk of death if they do not receive a transplant** and on each candidate's **transplant benefit**. In the proposed allocation system, a candidate's transplant benefit will be measured as the difference between the expected days lived during the first year following a transplant and the expected days lived during an additional year on the waitlist.

- The allocation scores will be computed using a variety of **clinical** variables **that are found among transplant candidates.** The factors used in the allocation system are based on clinically important and objective measures of disease severity and physiologic reserve. Factors common among transplant candidates are included along with factors that distinguish differences among broad categories of illness.

- The proposed system will assign each candidate an **allocation score that will determine his or her priority for receiving a lung offer**.

- **Candidates of any age, sex, race/ethnicity, and diagnosis are represented among those likely to be offered donor lungs by the new system.**

- **Pediatric candidates under age 12 will continue to receive lung offers based on their waiting time; they also will receive first priority for lungs from donors under age 12 and will have improved access to lungs from adolescent donors.**

- **In an effort to address issues of growth and development delays and post-transplant survival outcome for older pediatric patients, adolescent (12-17 years) candidates will be assigned first priority for adolescent donor lung offers.**

- **Centers may update diagnostic information on transplant candidates at any time** to correspond with changes in their medical condition; the Committee continues to evaluate possible requirements for periodic **updates of diagnostic information for each candidate**.

- The Thoracic Committee will continually revise and improve the lung allocation algorithm through periodic data analysis of updated patient populations. The Committee will undertake review and revision of the algorithm every six months.

C. How the System Works

A Subcommittee of the Thoracic Organ Transplantation Committee formed to evaluate the national system of lung allocation developed a lung allocation algorithm by using the most current data available from the OPTN database. The Subcommittee assessed clinical predictors of illness severity associated with actual candidates on the lung waiting list, and built a model to describe candidates' probability of survival both on the waitlist and after a lung transplant.

For each lung transplant candidate, the algorithm uses a set of clinical, demographic, disease severity, and physiologic reserve data to estimate how many days the candidate would live during the next year on the waitlist (waitlist urgency measure) and how many days the candidate would live during the first year after a transplant (post-transplant survival measure). The difference between these two estimates is used to create an individual measure of transplant benefit.

The algorithm then uses a balance of each candidate's waitlist urgency and transplant benefit to assign that candidate an allocation score. Each candidate's score then determines his or her priority for a lung offer in relation to other transplant candidates on the lung waiting list. In order for scores to reflect the current medical condition of candidates on the waitlist, transplant centers may update the candidate's clinical variables on the UNet[sm] system at any time to reflect changes in medical condition that may affect candidate priority for a lung offer.

D. Differences from the Previous Proposal

In August 2003, the OPTN/UNOS Thoracic Committee and Lung Subcommittee released an earlier version of the lung allocation algorithm for public comment. After reviewing the commentary on the proposal from the lung transplant community, candidates, patient advocacy groups, and public, the Subcommittee made several major revisions to the system to clarify the policy, improve its accuracy, and reflect the concerns of those who responded with comments. Among the major differences from the prior proposal are:

- **Current survival data.** The algorithm will employ, on an ongoing basis, the most recent transplant candidate survival data available. The current proposal is based upon survival data from a cohort of <u>all types of transplant candidates</u> of age 12 and older listed for transplant between

1999 and 2001. The earlier proposal used a data cohort of candidates listed for transplant between 1997 and 1998

- **Pediatric preferences.** Pediatric patients under age 12 will now receive a first-offer preference for lungs procured from donors under age 12 and second-offer preference for lungs procured from donors age 12-17. Pediatric patients from age 12-17 will now receive a first offer preference for lungs procured from donors age 12-17 and second-offer preference for lungs procured from donors under age 12.

E. The Future of the Lung Allocation Algorithm

An essential feature of this policy is the plan to regularly review additional data gathered by the new system to generate continuous quality improvement of the survival models. The Committee and Subcommittee believe that the current proposal uses the best models of survival available from current data. However, the Committee will review the lung allocation policy and methodology on a regular basis. The Committee anticipates that entry of additional data elements needed to maintain candidates' waitlist priority will allow further refinements of the models.

As additional data are collected, the Committee and Subcommittee will regularly review and revise the algorithm to reflect changes in waitlist and post-transplant outcomes. The Committee and Subcommittee expect that this process will continually improve the quality of the lung allocation system over time to achieve its overall performance goals of minimizing waitlist mortality, increasing transplant benefit, and allocating lungs in an equitable manner.

2. Policy Goals

In designing the proposed lung allocation algorithm, the Lung Allocation Subcommittee focused on established tangible performance goals that it hoped to achieve by revising the method by which donor lungs are allocated to patients on the waitlist. The primary goals of the proposed policy are to reduce the number of deaths on the waitlist, to increase transplant benefit among lung transplant recipients, and to ensure the efficient and equitable use of the scarce resource of donor lungs. The Committee believes that the proposed system would reduce mortality among transplant candidates by prioritizing candidates with high waitlist urgency and with good expected post-transplant outcomes.

Organ allocation to the highest risk candidates would not be efficient if organs were allocated to candidates who were unlikely to survive and whose lives could not be prolonged by transplantation. Therefore efficient use of donor organs requires consideration of expected lifetimes both with and without a transplant. The Committee expects to achieve its stated goals by implementing an allocation system that prioritizes candidates for organ offers based on a balance between transplant benefit and waitlist urgency. The Committee will be able to evaluate achievement of the algorithm's performance goals by reviewing on a regular basis the impact of the algorithm on both waitlist death rates and post-transplant survival rates.

3. Background

The proposed lung allocation algorithm is the latest step in an ongoing body of work to create a risk-stratified lung allocation system. It is responsive to the OPTN Final Rule (42 CFR Part 121) as it focuses upon evaluation of candidate medical urgency as well as system utility and efficiency. In 1990, the OPTN/UNOS Board of Directors approved a separate policy to allocate donor lungs based solely on the amount of time candidates waited on the waitlist. The system operated by allowing candidates who had accrued the greatest amount of waiting time on the list to have the highest priority in receiving lung offers. This policy has remained virtually unchanged since that time, with one notable exception. In 1995, the Board took a step toward creating a risk-stratified lung distribution system by recognizing a higher mortality rate among candidates with idiopathic pulmonary fibrosis (IPF) and allowing candidates with that diagnosis to receive 90 additional days of accrued waiting time.

In 1999, the OPTN/UNOS Thoracic Organ Transplantation Committee and the Lung Allocation Subcommittee began to evaluate the lung allocation system, and recognized a need for change that would ensure that the scarce resource of donor lungs would be allocated more efficiently to reduce wait-list mortality. The Committee determined that a risk-stratified system that would distribute lungs based on the urgency of candidates' illnesses was the solution. At that time, the Committee considered whether waiting time and wait list mortality issues could be addressed through classification of medical urgency leading to prioritizing lung candidates based on the severity of their illness. However, the fact that each type of lung disease demonstrates a different indicator for determining the severity of a candidate's illness prevented the development of a status system. The Subcommittee then studied the probability of survival on the lung waiting list using a multivariate analysis of physiological data collected by UNOS on candidates at the time of listing. By November 2000, this ongoing analysis had revealed to the Subcommittee that the most significant predictor of pre-transplant mortality is diagnosis at the time of listing.

In November 2000, the Subcommittee agreed to propose a plan to serially collect data elements from lung transplant candidates on the waitlist in addition to those already collected by UNOS in order to further develop a more inclusive risk-stratified system. A proposal was submitted for public comment that would have required transplant centers to collect additional variables on lung transplant candidates at the time of listing and serially thereafter. This proposal met with significant resistance from the transplant community and was never enacted. Regardless, the Subcommittee continued to perform analyses and base its planned lung allocation system around the variables that are collected by UNOS at the time candidates are listed.

In 2001, the Lung Allocation Subcommittee met several times to further refine the plan for a risk-stratified lung allocation system. Over the course of these meetings, the Subcommittee reached a consensus that an ideal organ allocation algorithm would rank potential recipients by their risk of mortality on the waiting list coupled with and balanced by their risk of mortality within the first year after a transplant. That year, the Subcommittee presented the Board of Directors with a resolution, to approve, in principle, a change from the lung allocation system based on wait time, to a risk-stratified lung allocation algorithm. Over the next year, the Lung Allocation Subcommittee worked to refine the data analysis to determine the pre-transplant variables that are most predictive of mortality among each disease group awaiting transplant.

By November 2002, after continued data analysis, the Lung Allocation Subcommittee had neared completion of the proposed lung allocation algorithm. In March 2003, the Subcommittee held the Conference on Lung Allocation Policy to present the proposed lung allocation system to the national lung transplant community, including surgeons, physicians, transplant coordinators, transplant administrators, and candidate advocates from around the country. Many of the attendees who took part in this public forum expressed support for the Subcommittee's goal of replacing the current waiting time-based allocation policy with a new risk-stratified allocation policy and offered comments and suggestions for improvement of the national lung allocation system. Following the conference, the Lung Allocation Subcommittee worked to incorporate many of the suggestions it received during the conference in the final proposal for a new risk-stratified lung allocation system that considers each waitlist candidate's clinical factors and allocates lungs based on a balance of each candidate's medical urgency prior to transplant and their transplant benefit following lung transplantation.

In August 2003, the Thoracic Committee released a proposal for public comment that proposed an initial lung allocation algorithm. The algorithm was similar to the one now proposed in that it assigned priority to transplant candidates based on waitlist urgency and transplant benefit. However, this prior lung model was based on four major illness groups and operated on survival rates from 1997 and 1998. These factors of the proposal were not widely accepted by physicians or candidates alike in the lung transplant community. Following the public comment period, and in response to the feedback from the community, the Lung

Allocation Subcommittee and the Thoracic Committee revised its proposal to lessen the focus upon separate diagnosis groups and, instead, use a single unified allocation model incorporating all of the patient categories. As you read this document, please note these changes from the prior proposal.

In addition, please note the change in pediatric allocation priority in this proposal. For both younger pediatric and adolescent lung candidates, growth and development issues, as well as mortality risk, factor into the need for timely transplant. This proposal attempts to address pediatric urgency and improved opportunities for transplantation through assigned allocation preference. This change was made as a result of the efforts of the Joint Pediatric-Lung Allocation Subcommittee and feedback from the pediatric lung transplant community.

4. How the Proposed System Assigns Priority for Lungs

The proposed lung allocation algorithm will assign priority for donor lungs to candidates age 12 and older based on a calculation of the medical urgency of patients on the waitlist and the projected transplant benefit after transplantation. A candidate's **waitlist urgency** is measured by the expected days of life during the next year that would result if the candidate did not receive a transplant (remained on the waitlist). A candidate's **post-transplant survival** is measured by the expected days lived during the first year post-transplant. The algorithm will assign a **Lung Allocation Score** to each patient active on the lung transplant waiting list. The **Lung Allocation Score** is calculated from the difference between a patient's **transplant benefit measure** (post-transplant survival measure minus waitlist urgency measure) and the patient's **waitlist urgency.** The calculation of the score is based on patient characteristics that have the same effect on mortality for all patients, and upon a few characteristics that have distinct effects for particular diagnosis groups. Patients under age 12 will continue to be allocated lungs based on waitlist time and ABO blood type.

Pediatric donor lungs (0-17 years) will be allocated preferentially to pediatric patients, as more specifically described in Section G below.

A. *Data and Analytical Methods*

In designing the proposed lung allocation model, the OPTN/UNOS Lung Allocation Subcommittee and the Scientific Registry of Transplant Recipients (SRTR) analyzed OPTN lung transplant candidate and recipient data. For the estimation of waitlist urgency, the Subcommittee studied patients listed for their first transplant between January 1, 1999, and December 31, 2001.[1] For the estimation of post-transplant survival, candidates who received a lung transplant between January 1, 1999, and December 31, 2001, were studied. Analysis of pediatric candidates suggested that recipients age 12 and older were similar to adults in terms of waitlist survival and post-transplant outcomes. Candidates under age 12 had different diagnoses and outcomes. Thus, it was decided to consider children under age 12 separately. These young pediatric candidates (under age 12) were not included in the models described below.

One model (Cox proportional hazards) was developed for all candidates age 12 and older to predict the likelihood of death on the waiting list, based on the characteristics of each candidate. A second proportional hazards model was developed for all patients age 12 and older to predict the probability of post-transplant survival. These models were created using variables collected on the OPTN Transplant Candidate and Recipient Registration forms at the time lung transplant candidates are placed on the waiting

[1] The current lung allocation proposal uses survival data from 1999-2001 for all candidates. In response to public comment, the Committee determined that the accuracy of the lung allocation model would be improved through the use of survival data that reflects recent advances in disease treatments and higher survival rates.

list and those collected at the time of transplant, respectively. These factors included measures of disease severity, physiologic reserve, and diagnosis. [2]

The analyses identified factors associated with waitlist urgency and factors associated with post-transplant survival. For the purposes of identifying risk factors that had distinct effect in candidates with particular diagnoses, transplant candidates were classified into four major diagnosis groups. The diagnosis groups were categorized into four broad groups based on the clinical characteristics of the various diagnoses for candidates awaiting lung transplantation and on existing data for the survival patterns in these candidates. Within each group are various illnesses that share similar clinical characteristics and/or similar risk factors for urgency on the waitlist and survival following a transplant. The groups are as follows:

- **Group A** consists of candidates age 12 and older with obstructive lung disease. Group A includes chronic obstructive pulmonary disease (COPD), such as alpha-1-antitrypsin deficiency and emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean PA pressure ≤ 30 mmHg. [3]
- **Group B** consists of candidates age 12 and older with pulmonary vascular disease. Group B includes primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases.
- **Group C** consists of candidates age 12 and older with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.
- **Group D** consists of candidates age 12 and older with restrictive lung diseases. Group D includes idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant).

With every candidate assigned to a diagnosis group, additional analyses were undertaken to identify specific risk factors that varied by diagnosis group. Hazard ratios associated with these factors were calculated based on data from all lung candidates listed and transplanted during this time interval.

B. *Pre-Transplant Factors in the Proposed Lung Allocation Algorithm*

The proposed lung allocation algorithm operates by assigning priority to transplant candidates based on a balance of waitlist urgency and transplant benefit. The first step in this process is to evaluate each candidate's risk of death on the waitlist (waitlist urgency). Measures of disease severity and physiologic reserve were evaluated and those that were important predictors of waitlist urgency were identified. (See Table 1.) The factors found to predict waitlist mortality (urgency) for all candidates were: forced vital capacity (FVC), ventilator use, body mass index (BMI), insulin dependent diabetes, 6-minute walk distance, New York Heart Association (NYHA) functional classification, and disease diagnosis. There were several additional factors that were either important in certain diagnosis groups but not others, or had varying effects in different diagnosis groups. Those include age, O_2 required at rest, and pulmonary artery systolic pressure.

[2] The completion of the lung data collection project described in Section 5.A of this proposal is expected to add more variables to those thirty already analyzed by the Committee. Additional variables reflecting disease severity and patient physiologic reserve will be evaluated by the Committee for incorporation into the lung allocation algorithm as these variables are identified or become available.

[3] Candidates with alpha-1-antitrypsin deficiency are included in Group A along with COPD. The Lung Subcommittee reviewed the concerns of this patient population with the prior lung algorithm proposal. Upon review the Subcommittee determined that, if classified as its own separate diagnosis, alpha-1-antitrypsin deficiency candidates as a whole would be disadvantaged and would receive considerably lower allocation scores on their own than if they were included with Group A and COPD candidates. Thus, the Lung Subcommittee decided that Group A would continue to include alpha-1-antitrypsin deficiency based on the obstructive properties of the disease.

Table 1.

Factors Used to Predict Risk of Death on the Lung Transplant Waitlist
1. Forced vital capacity (FVC)
2. PA systolic (Group A, C, D)
3. O_2 required at rest (Group A, C, D)
4. Age
5. Body mass index (BMI)
6. Insulin dependent diabetes
7. Functional status (New York Heart Association class)
8. 6-minute walk distance
9. Ventilator use
10. Diagnosis (see section D for details)

Lower FVC, lower BMI, ventilator use, insulin–dependent diabetes, higher NYHA class, and 6 min. walk distance < 150 ft were associated with higher waitlist mortality risk. The analyses also revealed that for groups A, C, and D, higher O_2 requirement at rest and higher pulmonary artery systolic pressure were associated with higher mortality risk on the waitlist, but that these were not risk factors for patients in Group B.

C. *Post-Transplant Factors in the Proposed Lung Allocation Algorithm*

As noted above, the proposed lung allocation system operates by assigning priority to lung transplant candidates based on a balance of waitlist urgency and transplant benefit. Since the calculation of the transplant benefit measure involves post-transplant survival, the second step in the proposed lung distribution algorithm, therefore, is the computation of each candidate's expected survival following a transplant. The analyses evaluated measures of disease severity and physiologic reserve and identified those that were important predictors of post-transplant survival. (See Table 2.) The predictive factors for post-transplant survival across all patients were ventilator use, age, creatinine, New York Heart Association functional classification, and diagnosis. Two factors were important in certain diagnosis groups but not others, or had varying effects among the diagnosis groups. These factors were forced vital capacity (FVC), and pulmonary capillary wedge pressure (PCW) ≥20 mmHg.

Table 2.

Factors That Predict Survival After Lung Transplant
1. Forced Vital Capacity (FVC) (Group B, D)
2. PCW pressure ≥ 20 (Group D)
3. Ventilator use
4. Age
5. Creatinine
6. Functional Status (NYHA class)
7. Diagnosis (see section D for details)

Analyses showed that older age, higher creatinine, ventilator use, and higher NYHA class were associated with higher post-transplant mortality risk. The analyses also showed that in groups B and D, lower FVC was associated with higher post-transplant mortality risk. In group D only, PCW $\geq$ 20 mm/Hg was associated with higher post-transplant mortality risk.

D. *Use of Diagnosis as a Factor in Allocation*

As indicated in the previous two sections, diagnosis is an important predictor of both urgency on the waitlist and post-transplant survival. The proposed lung allocation system includes several individual diagnoses as risk factors (see Table 3). Note that no diagnoses are excluded from the allocation algorithm. The use of selected diagnoses in the algorithm allows for variation in urgency and survival risks for patients with these diseases from the rest of the disease populations. The overall waitlist and post-transplant mortality risks for patients with COPD, Bronchiectasis, Sarcoidosis, LAM, pulmonary hypertension, Eisenmenger's Syndrome, cystic fibrosis, idiopathic pulmonary fibrosis, pulmonary fibrosis (other), and obliterative bronchiolitis are factored into the algorithm for organ offers. Candidates who do not fall into one of these categories are included with other candidates in their major diagnosis group A, B, C, or D as described in Section 3.A.

Table 3.

Diagnoses Used in Lung Pre-Transplant And Lung Post-Transplant Models

Four diagnosis groups allow different risk factor effects:

- Group A (COPD + others)
- Group B (PPH + others)
- Group C (CF + others)
- Group D (IPF + others)

Additional differences in levels of risk were identified for the following specific diagnoses:

- Obliterative bronchiolitis and bronchiectasis
- Eisenmenger's
- Lymphangioleiomyomatosis
- Obliterative bronchiolitis (non retransplanted)
- Pulmonary fibroses (other)
- Sarcoidosis with PA mean > 30 mm/Hg
- Sarcoidosis with PA mean $\leq$ 30 mm/Hg

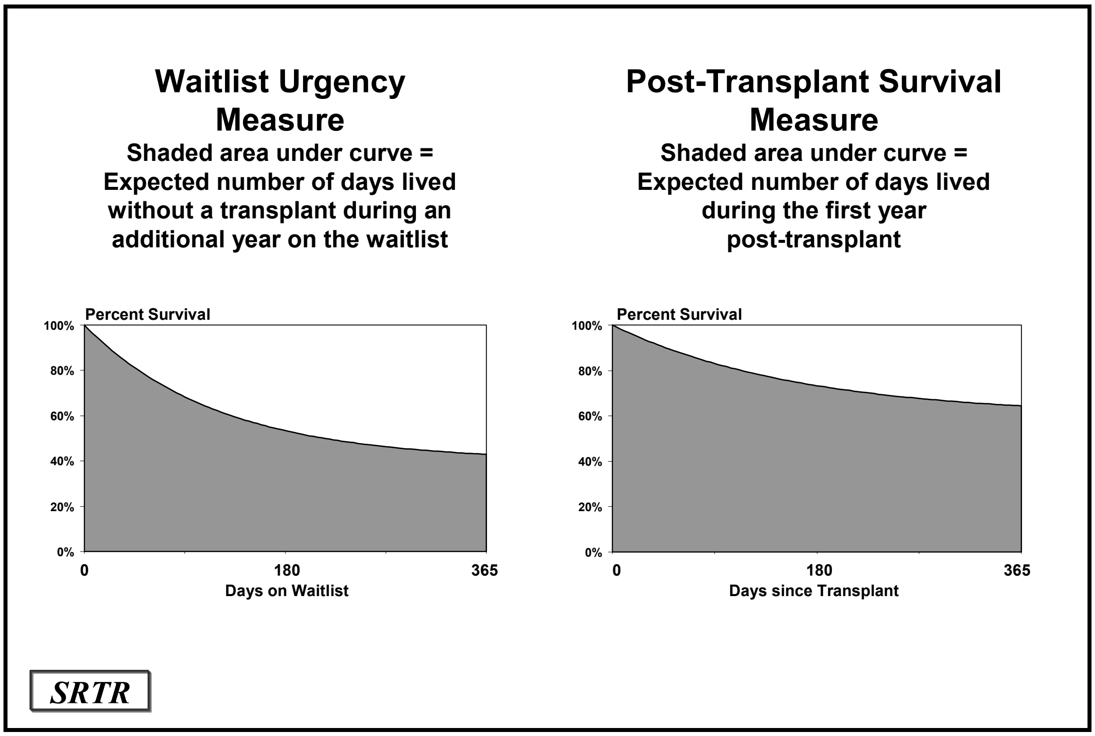
E. *Mechanics of the Proposed Lung Allocation Algorithm*

A lung transplant candidate's **waitlist urgency** is measured by the expected days of life during the next year that would result if the candidate did not receive a transplant (remained on the waitlist). A candidate's **post-transplant survival** is measured by the expected days of life lived during the first year post-transplant. A candidate's **transplant benefit** is measured by the difference between the candidate's post-transplant survival measure and their waitlist urgency measure. The proposed lung allocation algorithm uses clinical characteristics of the individual transplant candidate to predict that candidate's waitlist urgency, or, in other words, the expected survival during an additional year if the candidate remains on the waitlist.[4] The proposed algorithm also uses the same method to calculate that candidate's expected post-

[4] In response to public comment to the prior proposal, the Committee considered whether to use 1-year or 2-year waitlist urgency measure in the algorithm. Allocation scores were not significantly different using

transplant survival during the first year following transplant[5]. The expected survival measures are derived from Cox models for the clinical variables outlined above and are specific to the characteristics of each transplant candidate.[6] A candidate's waitlist urgency measure and post-transplant survival measure are illustrated graphically as survival curves in Figure E.1. The areas under the two survival curves over the next year are equivalent to the expected number of days that a patient would live during the additional year on the waitlist and the expected number of days that the patient would live during the first year after a transplant, respectively.

Figure E-1



---

these two alternative calculations. The Committee then chose to build the current proposed lung algorithm around the 1-year waitlist survival calculation so that the algorithm could function with the most current data.

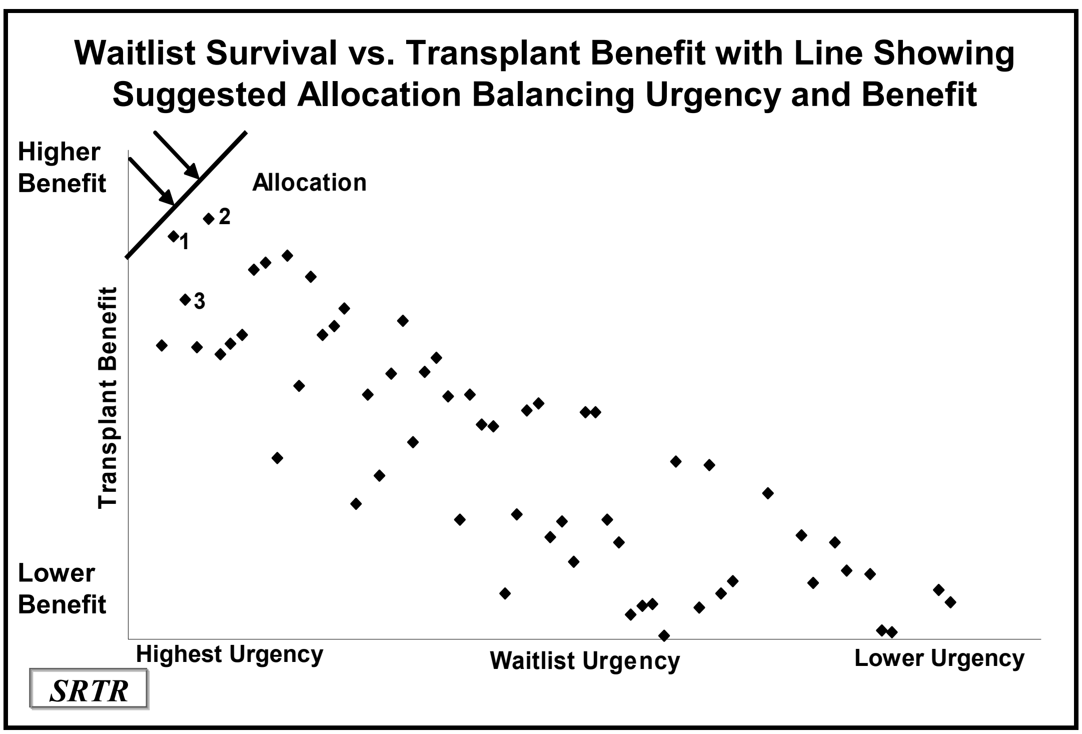
[5] In response to public comment to the prior proposal, the Committee considered whether to use 1-year or 2-year post-transplant survival measure in the algorithm. Allocation scores resulting from these two alternative calculations were in very close agreement (correlation greater than 0.999). The Committee then chose to build the current proposed lung algorithm around the 1-year post-transplant survival calculation so that the algorithm could function with the most current data.

[6] One of the more common methods for analysis of survival data is the Cox proportional hazards method. This type of method allows you to determine how having a particular characteristic will change the risk of death. For example, the method allows you to determine that having a particular condition, such as a specific diagnosis, is associated with increased risk of death compared to someone without that diagnosis. The mathematical form of the Cox method requires that the increase in risk for a person with a particular characteristic when compared to a person without the characteristic is the same at every time point (i.e., proportional hazards). Another defining characteristic of this approach is that it does not require specifying the mathematical form of risk of death for the baseline population, the population without any of the risk factors.

The **transplant benefit** for a candidate is the expected extra days of life over the next year if that candidate were to receive a transplant rather than remain on the waitlist with no future transplant. The proposed allocation score is calculated from the difference between transplant benefit measure and waitlist urgency measure (based on the projected days of life during the next year without a transplant). This proposed scoring system addresses several goals simultaneously, which are motivated by the possibility that there may be several candidates on the list who may have a similar transplant benefit. Among candidates with similar transplant benefit, the Committee decided to assign a higher priority to those candidates with higher medical urgency on the waitlist. This feature of the proposal is designed to improve the likelihood that lungs are offered in a timely manner to candidates with high benefit by giving higher priority to those high benefit candidates who are more likely to die if they must wait for the next organ rather than being offered the current organ.

The proposed scoring system gives equal weight to transplant benefit and waitlist urgency. To show how the system would work, transplant benefit was plotted against waitlist urgency for a hypothetical group of candidates (Figure E-2). The proposed allocation score corresponds to moving a 45° line from the upper left corner to prioritize candidates in the order that the line reaches them on the plot. Figure E-2 shows the ranking of the first three candidates (identified by integers 1, 2, and 3 near the points on the plot) that would be prioritized with the proposed system. The Thoracic Committee determined that it was appropriate to give **equal weight to waitlist urgency as to transplant benefit** as the patient with a lower waitlist urgency (but similar benefit) would be more likely to live longer and have the opportunity to receive subsequent lung offers. Because the allocation scores can be calculated to an infinite number of decimal places there will be no tied scores among lung transplant candidates, with the exception of scores of zero. Time accrued on the waiting list will be used to determine priority among any candidates with scores of zero for a period of time following implementation of the proposal as more specifically described in Section 4.H below.

Figure E-2



The proposed algorithm may be understood by considering the following two definitions:

Waitlist Urgency Measure

Expected number of days lived without a transplant during an additional year on the waitlist

Post-transplant Survival Measure

Expected number of days lived during the first year post-transplant

The proposed algorithm will then compute a **transplant benefit measure** for each lung transplant candidate by performing the following calculation:

Transplant Benefit Measure

Post-transplant Survival Measure minus Waitlist Urgency Measure

A **raw allocation score** will then be computed for each lung transplant candidate by performing the following calculation:

Raw Allocation Score

Transplant Benefit Measure minus Waitlist Urgency Measure

Finally, the proposed algorithm will use each candidate's raw allocation score to compute a normalized **Lung Allocation Score** from 0 to 100 by performing the calculation in the following box, and the resulting scores will be used to create a ranked list of candidates:

$$\text{Lung Allocation Score} = \frac{[100 \times \text{Raw Allocation Score} + (2 \times 365)]}{3 \times 365}$$

To illustrate the operation of the proposed system, consider the following example: Assume that a donor lung is available, and both Patient X and Patient Y are on the waiting list. Taking into account all diagnostic and prognostic factors, Patient X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Patient X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Patient Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize patients based on the difference between each patient's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

	Patient X	Patient Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
e. **Lung Allocation Score**	**74.3**	**78.0**

In the example here, Patient X's raw allocation score would be 84.1 and Patient Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by patients and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Patient X's raw allocation score of 84.1 normalizes to a **Lung Allocation Score** of 74.3. Patient Y's raw score of 124.5 normalizes to a **Lung Allocation Score** of 78.0. As in the example of raw allocation scores, Patient Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Patient X.

Under the proposal, each lung waitlist candidate's **Lung Allocation Score** on the normalized 0-100 scale will maintain decimal places so that tied scores do not occur. In addition to the **Lung Allocation Score**, a percentile ranking will be available to illustrate the relative placement of their score in relation to other candidates on the waitlist.

F. *Equity of the Lung Allocation Score*

Equity of the proposed policy was shown by demonstrating a large overlap in lung allocation scores among 2,233 candidates age 12 or above who were active on the lung waiting list on January 1, 2003. Figures F-1 to F-4 show the distribution of lung allocation scores by gender, race/ethnicity, diagnosis group and age, with the scores calculated using the proposed algorithm, as noted in Section E above. In all figures, higher lung allocation scores (y-axis, not labeled) correspond to higher priority for receiving a transplant. There is a large overlap in lung allocation scores among groups by gender, race/ethnicity, diagnosis, and age.

Figure F-1

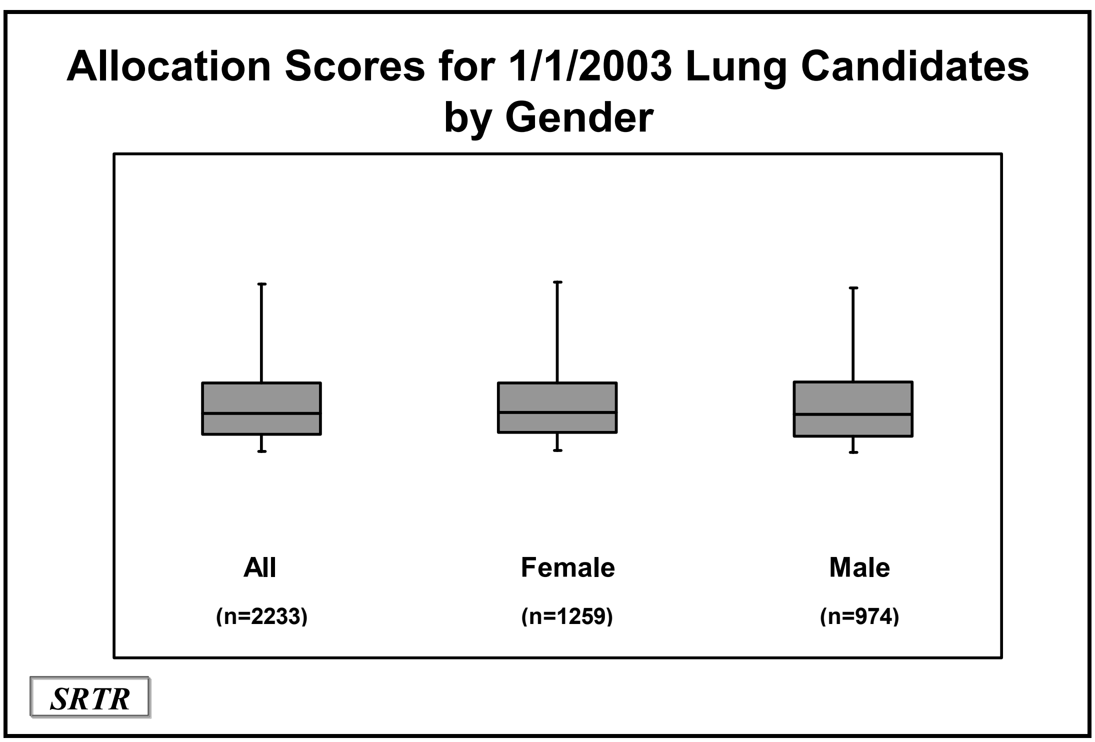


Figure F-2

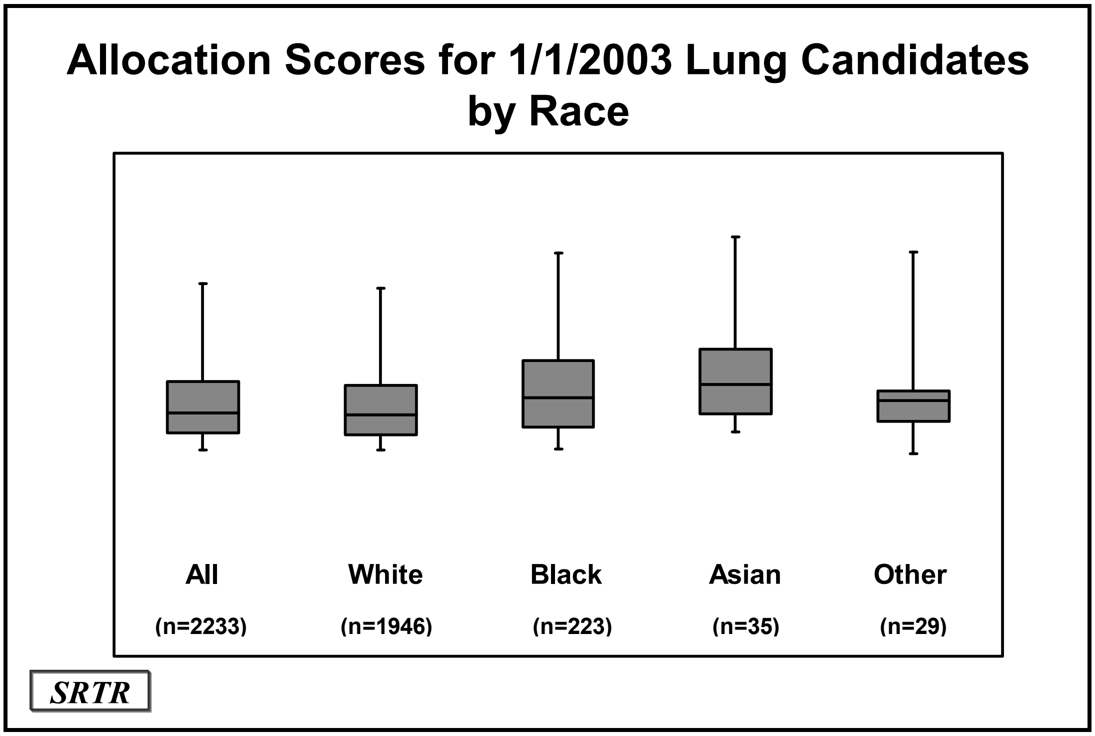


Figure F-3

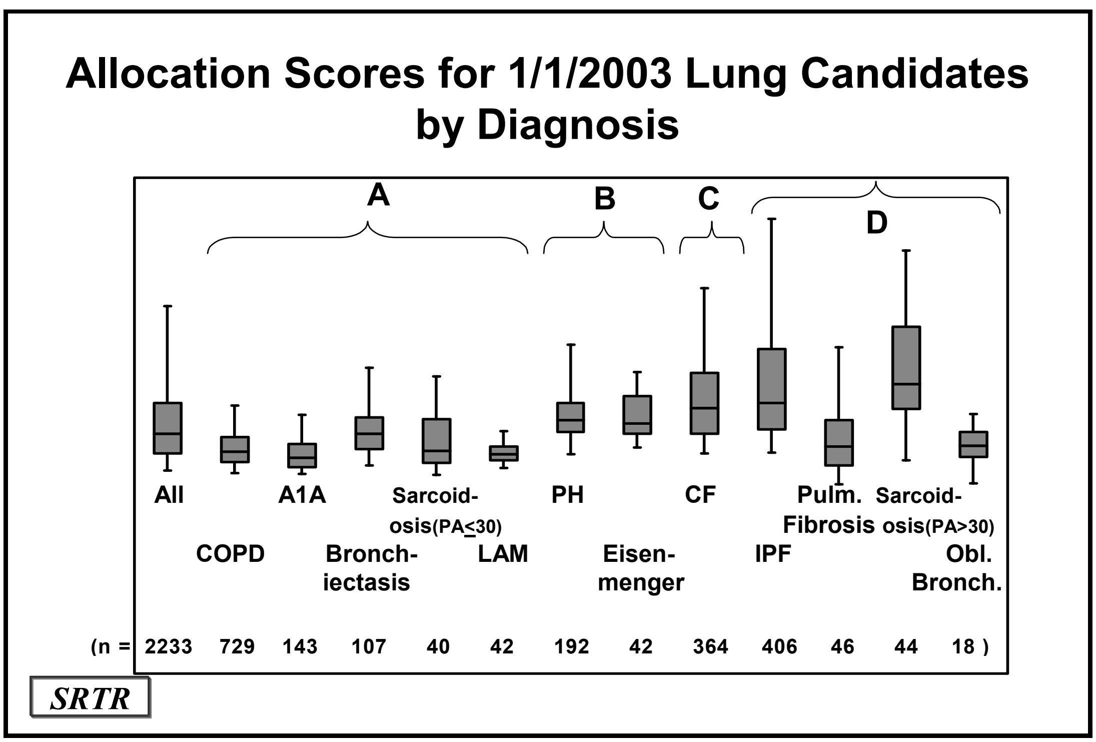
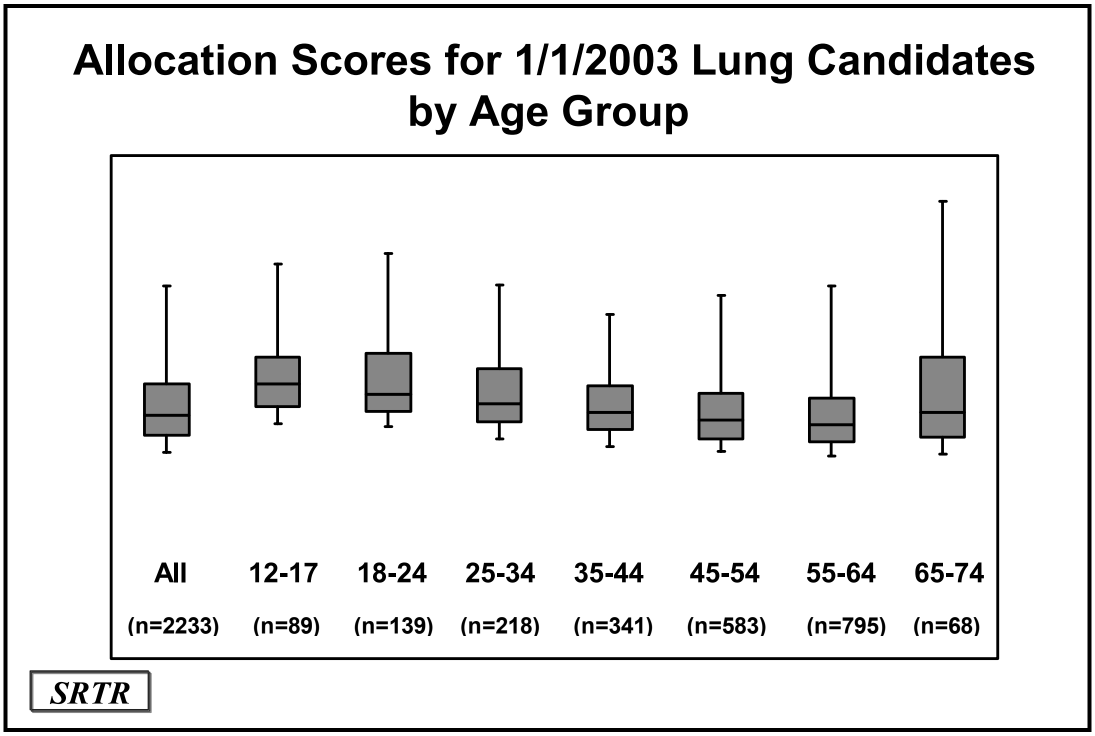


Figure F-4



G. *Pediatric Candidates and Pediatric Donors*

Pediatric candidates make up a small but important percentage of the lung transplant waitlist. In determining how best to allocate donor lungs to this group, the Subcommittee examined, by age, candidates on the OPTN waitlist to determine the incidence of diagnosis, patterns of outcomes, and the impact of patient age on waitlist mortality and outcomes. From this analysis, the Subcommittee determined that pediatric lung candidates age 12 years and older were similar in spectrum of diagnosis and outcome to adult lung candidates. The data also demonstrated that pediatric candidates under age 12 had a different spectrum of diagnoses and outcomes from lung candidates 12 years and older. Upon further study of the available data, the Subcommittee found that, over the past seven years, only 135 lung transplants had been performed on patients under age 12. Of that number, 92% were transplanted with lungs recovered from donors under age 12.

Based on the analysis outlined above, the Lung Allocation Subcommittee, divided pediatric candidates into two groups: adolescent candidates (12-17 years) who will receive offers based on Lung Allocation Score along with adult candidates, and young pediatric candidates (0-11 years) who will receive offers based on waiting time. When young (age 0-11) candidates reach age 12, they will be prioritized for donor lungs based on their Lung Allocation Score.

The age demarcation for pediatric candidates was also created to allow for practical considerations; size is an important factor in assessing donor lung suitability. Most younger pediatric donor lungs are best suited for a younger pediatric candidate of similar size. The Subcommittee also noted that it is rare in clinical practice to reduce the size of adult donor lungs for transplant into a young pediatric candidate.

The OPTN/UNOS Pediatric Transplantation Committee supported the goals of the lung proposal submitted for public comment in August 2003, but was concerned that the lung allocation algorithm, as then written, did not fully address issues of importance to ensure equitable lung allocation to pediatric candidates. Pediatric patients experience specific challenges when waiting for transplant. Children and adolescents face ongoing growth failure and development issues that increase urgency for transplant. In order to address these concerns, the Pediatric and Thoracic Committees established the Joint Pediatric-Lung Allocation Subcommittee. Through the collaborative efforts of the Joint Subcommittee, the current lung allocation proposal recognizes these pediatric needs and differences by assigning levels of pediatric preference in the allocation of pediatric donor lungs.

The proposed lung allocation algorithm will offer adolescent (age 12-17) donor lungs first to adolescent candidates (age 12-17) based on their Lung Allocation Score, then to candidates age 0-11 based on waiting time, and finally to adult candidates (age 18+) based on their Lung Allocation Score. Lungs from young pediatric donors (age 0-11) will be offered first to candidates aged 0-11 by waiting time, then to adolescent candidates based on the Lung Allocation Score, finally to adult candidates based on their Lung Allocation Score. Lungs from donors age 18 and older will be offered first to candidates 12 years old and older based upon their Lung Allocation Score, and then to younger pediatric candidates 0 – 11 years based upon their waiting time.

A similar allocation sequence was modeled by the SRTR and reviewed by both the Pediatric and Thoracic Committees. In the statistical simulation model of a proposed allocation system with assigned adolescent and young pediatric candidate preference, the number of lungs transplanted into pediatric recipients more than doubled from the model's projections for the current system. The model shows that the proposal first submitted for public comment also would increase the number of pediatric lung transplants. The number of pediatric lung transplants is highest under the system most similar to the present proposal assigning preference for children in the allocation of all pediatric donor lungs. The Committees were cautioned to assess trends suggested by the model rather than actual numbers, which for children are expected to be small relative to adults. Finally, the analysis suggests a decrease in lung waitlist deaths and increase in lung post-transplant deaths with either of the modeled proposed systems. Differences between the two modeled proposed systems are relatively small. The Committees concluded, therefore, that the present proposal provides greatest opportunity for additional pediatric transplants with minimal, if any, expected disadvantage to pediatric or adult patient survival.

Assigning priority to pediatric lung candidates follows a precedent established by and currently used in other organ allocation systems. Currently, in the allocation systems for kidney, liver, and heart, pediatric (0-17 years) candidates are assigned some form of priority to address and acknowledge the growth and development concerns as well as, in the case of liver and heart, the benefit of effective matching for age to improve post-transplant function and survival.

Adolescents make up approximately twenty percent of all deceased lung donors 12 years and older. When compared to adults on the waiting list, a higher proportion of children and adolescents die awaiting lung transplants and a smaller proportion receive lung transplants. The proposed lung allocation system, with assigned pediatric preference, may help to improve the opportunity for transplant for adolescent candidates. The Joint Pediatric-Lung Allocation Subcommittee and full Committees acknowledge that the proposed system will not directly address improving access to donor lungs for younger pediatric (0-11years) candidates. The Joint Pediatric Lung Allocation Subcommittee is committed to exploring additional options, including development of a waitlist urgency/transplant benefit system for younger pediatric patients. Hopefully, as additional data are collected as a result of the implementation of this proposal, development of suitable models for this age group will become possible. Once developed, such models would be recommended as further enhancements to the policy.

H. *The Role of Accrued Waiting Time*

Because the proposed system prioritizes lung transplant candidates age 12 and older based on their survival benefit and waitlist urgency, waiting time will not play a role for this group in the proposed lung allocation system. Waiting time accrued by transplant candidates aged 12 and older on the lung waitlist will not alter their priority for organ allocation under the proposed algorithm, with the exception of candidates with lung allocation scores of zero (candidates with no or incomplete data entered by the implementation date will receive a Lung Allocation Score of zero). Time accrued on the waiting list as of the proposed system's implementation date will be used to determine priority for lung offers among these candidates for a period of six months at which time the mechanism for assigning allocation priority among candidates with scores of zero will be re-evaluated. This permits candidate waiting time accrued as of the time of policy implementation to continue to have some impact in lung allocation for candidates age 12 and older for some time, but anticipating that a more clinically relevant method for assigning priority among patients with lung allocation scores of zero will be developed as experience with the system is gained. Waiting time will continue to play a role for candidates under age 12, as those candidates will continue to be prioritized for lung allocation according to the amount of time they have accrued on the waiting list and their ABO type.

I *Entry of Candidate Variables*

To ensure that candidates receive allocation priority accurately reflective of their waitlist urgency and transplant benefit, it is important that candidate clinical data are entered upon listing. These data include a number of variables. The values for some of the variables will be available as a result of current requirements for waitlisting. It is expected that values for remaining required variables will be available for almost any patient considered to be an eligible candidate for lung transplantation. These variables will need to be entered into the system as part of the waitlisting process. Finally, there may be candidates whose medical condition precludes the performance of a test that is required to obtain a value for a variable. The Subcommittee determined that only in this last situation is the absence of actual candidate data acceptable. The Subcommittee developed the following rules to address each of the possible scenarios:

- No candidate clinical data upon listing: The candidate would be assigned a Lung Allocation Score of zero. Candidates with a Lung Allocation Score of zero will have the lowest priority compared to all other candidates with Lung Allocation Scores.
- Incomplete candidate clinical data upon listing: The candidate would be assigned a default value for each incomplete variable field. The value that results in the lowest contribution to the Lung Allocation Score for that variable field will be selected for the candidate.
- Candidate medical condition precludes test necessary to obtain clinical data: In the case of a required value for a test or procedure that cannot be safely performed UNet[sm] would be programmed to permit an override by the listing transplant program, with permitted entry of a estimated value deemed medically reasonable. Candidates who have override values entered will be reviewed automatically by the Thoracic Committee to determine whether such override values are appropriate and whether additional action is warranted.

J *Updating Candidate Variables*

To further ensure candidates receive allocation priority appropriate to their actual waitlist urgency and post-transplant survival, it will be important that candidate clinical data not only are entered upon listing but that they are then kept up-to-date. Physicians would be permitted to update these data at any time they believe a change in patient medical condition warrants such modification. The Lung Subcommittee has discussed the possibility of requiring data updates at specified intervals. This may be necessary to ensure that candidates' lung allocation scores continue to reflect waitlist urgency and transplant benefit throughout the course of their treatment while waiting for a lung. There was concern, however, that certain procedures involved in acquiring these clinical values are invasive and would not ordinarily be repeated absent the proposal's mandate. It might be expected that opportunities for updating lung allocation scores will be more prevalent and have greater consequence at relatively higher score thresholds. It is not possible at this time, however, to know what these thresholds might be.

As an alternative to incorporating any requirement for periodic updates of candidate clinical data in the proposal at this time, the Lung Subcommittee decided to include this general discussion of the issue, along with notice that such a provision is being considered for future implementation. The Lung Subcommittee anticipates that once some experience with the allocation system is gained, one or more threshold lung allocation scores will be selected for required periodic updating of candidate medical data, at least those variables that do not require invasive testing. **Public comment with respect to this matter is strongly encouraged.**

K *Allocation of Heart-Lung Blocs*

Under the proposed lung allocation algorithm, heart-lung candidates will continue to appear on both heart and lung match runs. Heart-lung candidates aged 12 and above will receive a Lung Allocation Score as described above. Heart-lung blocs will be allocated according to the existing policy for heart-lung allocation, Policy 3.7.7 (Allocation of Thoracic Organs to Heart Lung Candidates). It is intended that the proposed lung allocation algorithm will prioritize heart-lung candidates on the waiting list in conjunction with the isolated lung transplant candidates.

L *Implementation of the Proposed Lung Allocation Algorithm and Transitioning of Candidates on the Waiting List*

The Lung Subcommittee anticipates that the proposed lung allocation algorithm will be implemented upon final approval by the OPTN/UNOS Board of Directors and upon completion of computer programming. At that time, the proposed lung allocation will apply to all candidates already registered on the lung waitlist and all candidates who register on the waitlist thereafter. Transplant centers will be notified of the policy modifications and provided a period of approximately six months to record necessary medical data in the UNet system for candidates listed at that time. Implementation of the algorithm itself would then follow by approximately three months.

To help ensure a smooth transition to the modified lung allocation algorithm and entry of candidates' medical values in preparation for implementation, the Committee determined that candidates who are already registered on the waitlist on the date of implementation and who have no or incomplete data will receive a Lung Allocation Score of zero. Candidates with a Lung Allocation Score of zero will have the lowest priority compared to all other candidates with Lung Allocation Scores; they will be prioritized within the group of candidates with scores of zero based on the waitlist time they have accrued as of the time of policy implementation and their ABO blood type.

5. Additional Proposals to Support the Ongoing Development of the Lung Allocation Algorithm

A. Data Collection

The proposed lung allocation algorithm is the first step in a continual process of improving the lung allocation system. A crucial part of its success is the ongoing evaluation of the diagnostic variables that are collected for lung transplant candidates. Echoing the concerns of the lung transplant community that more variables should be evaluated in relation to the lung allocation algorithm, the Lung Allocation Subcommittee, with the assistance of non-transplant pulmonologists, developed a plan to collect and evaluate specific lung variables. **(Attachment A).**

The Subcommittee proposed to abstract a set of lung diagnostic variables from the medical files of a selected cohort of transplant candidates and transplant recipients from centers around the country. Many of the variables proposed to be collected are not among those currently collected by UNOS on the Transplant Candidate Registration form. This additional retrospective data will be analyzed in conjunction with the proposed allocation system in order to further improve the system. The allocation algorithm will also be improved by the prospective ongoing collection of serial clinical data from transplant candidates and transplant recipients.

On June 26, 2003, the Board of Directors approved the following resolution:

> ** RESOLVED, that the OPTN/UNOS begin the retrospective collection of specific diagnostic variables … at selected lung transplant centers on a selected cohort of waitlisted and transplanted lung patients for the purpose of gathering the data necessary for the ongoing refinement and improvement of the proposed lung distribution algorithm.

The data collection portion of this project began in December 2003, and will be complete by April 2004. Analysis of the data gathered by the project will begin immediately thereafter.

B. Regular and Periodic Review

To further support the ongoing improvement of the lung allocation algorithm, the Lung Allocation Subcommittee and the full Thoracic Committee will conduct regular reviews of the lung algorithm and the associated policies pertaining to the allocation of lungs at approximate six-month intervals. **Risk factors used in the algorithm will be calculated from the most current 3-year cohort of patients for both waitlist urgency and post-transplant survival.** The Committee will continually assess factors affecting waitlist urgency and post-transplant survival to confirm the accuracy of hazard ratios, update survival by diagnosis, determine if different diagnostic factors should be used in the algorithm, and evaluate the impact of the algorithm on the number of deaths among transplant candidates and recipients. The Subcommittee and Committee believe that the ability to continually and rapidly update the calculation of Lung Allocation Score to account for the most recent data studied by the Committee is essential to ensure ongoing equity and efficiency in lung allocation. The Subcommittee and Committee propose, therefore, that upon recommendation by the Committee of changes to the variables determined to be important predictors of waitlist urgency and post-transplant survival, these changes will be implemented as part of the policy and reported retrospectively to the Board of Directors. This would mean that changes to the policy possibly impacting data submission requirements for programs and allocation priority for candidates in need of lung transplantation could be made without seeking public comment and without prior Board approval. **The Committee strongly encourages public comment with respect to this provision.**

6. Policy Proposal

At the January 23, 2004, meeting of the OPTN/UNOS Thoracic Organ Transplantation Committee, and the February 20, 2004, meeting of the Lung Subcommittee, the following policy amendments were approved to be submitted for public comment:

> RESOLVED, that the following proposed modifications to Policies 3.7.6 (Status of Patients Awaiting Lung Transplantation), 3.7.9.2 (Waiting Time Accrual for Lung Candidates with Idiopathic Pulmonary Fibrosis (IPF)), and 3.7.11 (Allocation of Lungs) be submitted for public comment.

3.7.6 **~~Status of Patients Awaiting~~ <u>Lung Allocation.</u>~~Transplantation~~** ~~All patients awaiting isolated lung transplantation are considered to be the same urgency~~

~~status for the purposes of thoracic organ allocation.~~ Candidates are assigned priority in lung allocation as follows:

3.7.6.1 Candidates Age 12 and Older. Candidates age 12 and older are assigned priority for lung offers based upon Lung Allocation Score, which is calculated using the following measures: (i) waitlist urgency measure (expected number of days lived without a transplant during an additional year on the waitlist), (ii) post-transplant survival measure (expected number of days lived during the first year post-transplant), and (iii) transplant benefit measure (post-transplant survival measure minus waitlist urgency measure). Waitlist urgency measure and post-transplant survival measure (used in the calculation of transplant benefit measure) are developed using Cox proportional hazards models. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed below in Tables 1 and 2. It is expected that these factors will change over time as new data are available and added to the models. The OPTN/UNOS Thoracic Organ Transplantation Committee will review these data in regular intervals of approximately six months and will update Tables 1 and 2 accordingly. Modifications to the tables will be reported to the OPTN/UNOS Board of Directors on a retrospective basis.

Table 1

Factors Used to Predict
Risk of Death on the Lung Transplant Waitlist

1. Forced vital capacity (FVC)
2. Pulmonary artery (PA) systolic (Group A, C, D[7])
3. O_2 required at rest (A, C, D)
4. Age
5. Body mass index (BMI)
6. Insulin dependent diabetes
7. Functional status (New York Heart Association (NYHA) class)
8. Six-minute walk distance
9. Ventilator use
10. Diagnosis

[7] **Group A** includes candidates with obstructive lung disease, including without limitation, chronic obstructive pulmonary disease (COPD), alpha-1-antitrypsin deficiency, emphysema, lymphangioleiomyomatosis, bronchiectasis, and sarcoidosis with mean pulmonary artery (PA) pressure ≤ 30 mmHg.
Group B includes candidates with pulmonary vascular disease, including without limitation, primary pulmonary hypertension (PPH), Eisenmenger's syndrome, and other uncommon pulmonary vascular diseases.
Group C includes, without limitation, candidates with cystic fibrosis (CF) and immunodeficiency disorders such as hypogammaglobulinemia.
Group D includes candidates with restrictive lung diseases, including without limitation, idiopathic pulmonary fibrosis (IPF), pulmonary fibrosis (other causes), sarcoidosis with mean PA pressure > 30 mmHg, and obliterative bronchiolitis (non-retransplant).

Table 2

Factors That Predict Survival After Lung Transplant
1. FVC (Group B, D[9])
2. PCW pressure ≥ 20 (Group D[9])
3. Ventilator use
4. Age
5. Creatinine
6. Functional Status (NYHA class)
7. Diagnosis

The calculations define the difference between transplant benefit and waitlist urgency: Raw Allocation Score = Transplant Benefit Measure – Waitlist Urgency Measure.

Raw allocation scores range from –730 days up to +365 days, and are normalized to a continuous scale from 0 – 100 to determine Lung Allocation Scores. The higher the score, the higher the priority for receiving lung offers. Lung Allocation Scores are calculated to sufficient decimal places to avoid assigning the same score to multiple patients.

As an example, assume that a donor lung is available, and both Patient X and Patient Y are on the waiting list. Taking into account all diagnostic and prognostic factors, Patient X is expected to live 101.1 days during the following year without transplant. Also using available predictive factors, Patient X is expected to live 286.3 days during the following year if transplanted today. On the other hand, Patient Y is expected to live 69.2 days during the following year on the waitlist and 262.9 days post-transplant during the following year if transplanted today. Computationally, the proposed system would prioritize patients based on the difference between each patient's transplant benefit measure and the waitlist urgency as measured by the expected days of life lived during the next year.

	Patient X	Patient Y
a. Post-transplant survival (days)	286.3	262.9
b. Waitlist survival (days)	101.1	69.2
c. Transplant benefit (a-b)	185.2	193.7
d. Raw allocation score (c-b)	84.1	124.5
e. **Lung Allocation Score**	**74.3**	**78.0**

In the example here, Patient X's raw allocation score would be 84.1 and Patient Y's raw allocation score would be 124.5.

Similar to the mathematical conversion of temperature from Fahrenheit to Centigrade, once the raw score is computed, it will be normalized to a continuous scale from 0-100 for easier interpretation by patients and caregivers (see formula above). A higher score on this scale indicates a higher priority for a lung offer. Conversely, a lower score on this scale indicates a lower priority for organ offers. Therefore, in the example above, Patient X's raw allocation score of 84.1 normalizes to a Lung Allocation Score of 74.3. Patient Y's raw score of 124.5 normalizes to a Lung Allocation Score of 78.0. As in the example of raw allocation scores, Patient Y has a higher Lung Allocation Score and will therefore receive a higher priority for a lung offer than Patient X.

3.7.6.2 Candidates Age 0 - 11. Candidates 0 – 11 years old are assigned priority for lung offers based upon waiting time.

3.7.6.3 Candidate Variables in UNet[sm]. Entry into UNet[sm] of candidate clinical data responding to the variables shown in Tables 1 and 2 above, as they may be amended from time to time, is required when listing a candidate for lung transplantation. Candidates with no clinical data upon listing are assigned a Lung Allocation Score of zero, the score with the lowest priority. Candidates with incomplete clinical data upon listing are assigned a default value for each incomplete variable field. The value that results in the lowest contribution to the Lung Allocation Score for that variable field will be selected for the candidate. Programs are permitted to override the system and enter a value deemed medically reasonable in the event a test needed to obtain an actual value for a variable cannot be performed due to the medical condition of a specific candidate. Use of the override feature results in an automatic review by the Thoracic Organ Transplantation Committee to determine whether the override values selected are appropriate and whether further action is warranted.

3.7.6.3.1 Candidate Variables in UNet[sm] upon Implementation of Lung Allocation Scores Described in Policy 3.7.6. Candidates registered on the lung Waiting List at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 with no or incomplete clinical data will receive a Lung Allocation Score of zero, the score with the lowest priority.

3.7.6.3.2 Updating Candidate Variables. Programs may update their candidates' clinical data at any time they believe a change in patient medical condition warrants such modification.

3.7.7 Allocation of Thoracic Organs to Heart-Lung Candidates (No changes)

3.7.8 ABO Typing for Heart Allocation (No changes)

3.7.8.1 Heart Allocation to Pediatric Candidates Registered Under Blood Type "Z." (No changes)

3.7.8.2 ABO Typing for Lung Allocation. Patients who have the identical blood type as the donor and are awaiting an isolated lung transplant will be allocated thoracic organs before patients who have a compatible (but not identical) blood type with that of the donor and are awaiting an isolated lung transplant.

3.7.9 Time Waiting for Thoracic Organ Candidates Calculation of the time a patient has been waiting for a thoracic organ transplant begins with the date and time the patient is first registered as active on the UNOS Patient Waiting List.

Waiting time will not be accrued by patients awaiting a thoracic organ transplant while they are registered on the UNOS Patient Waiting List as inactive. When time waiting is used for thoracic organ allocation, a patient will receive a preference over other patients who have accumulated less waiting time within the same status category. Where applicable, waiting time accrued by a patient for a single thoracic organ transplant (heart or single lung) while waiting on the UNOS Patient Waiting List also may be accrued for a second thoracic organ, when it is determined that the patient requires a multiple thoracic organ (heart-lung or double lung) transplant. In addition, where applicable, waiting time accrued by a patient for a multiple thoracic organ transplant while waiting on the UNOS Patient Waiting List may be transferred to the waiting list for a single thoracic organ transplant.

3.7.9.1 Waiting Time Accrual for Heart Candidates. Patients listed as a Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation if the patient is upgraded to a higher status. For example, a patient who is listed as a Status 2 for 3 months and then is upgraded to a Status 1A for one week will accrue one week of waiting time as a Status 1A. If the patient is downgraded to a Status 2 for another 3 weeks, then the patient will have 4 months of total accrued time. If the patient subsequently is upgraded for another week as a Status 1A, then the patient's Status 1A waiting time will be 2 weeks.

3.7.9.2 Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6 ~~**with Idiopathic Pulmonary Fibrosis (IPF)**~~. Waiting time accrued by lung candidates age 12 and older at the time of implementation of the Lung Allocation Score described in Policy 3.7.6 will be used to determine priority in lung allocation among candidates with Lung Allocation Scores of zero~~A lung transplant candidate diagnosed with IPF shall be assigned 90 days of additional waiting time upon the candidate's registration on the UNOS Patient Waiting List~~.

3.7.10 Sequence of Heart Allocation (No changes)

3.7.11 Sequence of Adult Donor Lung Allocation ~~**of Lungs**~~**.** ~~Patients~~ Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation ~~purposes~~. If one lung is allocated to a ~~patient~~ candidate needing a single lung transplant, the other lung will be then allocated to another ~~patient~~ candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to ~~patients~~candidates in Zone A, then to ~~patients~~candidates in Zone B, then to ~~patients~~candidates in Zone C, and finally to ~~patients~~candidates in Zone D. In each of those five geographic areas, ~~patients~~candidates will be grouped so that ~~patients~~candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to ~~patients~~candidates in that ABO identical type. If the lungs are not allocated to ~~patients~~candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining ~~patients~~candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for adult donor lungs is as follows:

i. First locally to ABO identical ~~patients~~candidates age 12 and older according to Lung Allocation Score in descending order;
ii. Next, locally to ABO compatible ~~patients~~candidates age 12 and older according to Lung Allocation Score in descending order;
iii. Next, locally to ABO identical candidates 0 – 11 years old according to length of waiting time;
iv. Next, locally to ABO compatible candidates 0 – 11 years old according to length of waiting time;
v. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
vi. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;
vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of waiting time;
viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of waiting time;
ix. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
x. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;
xi. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of waiting time;
xii. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of waiting time;
xiii. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
xiv. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;
xv. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of waiting time;
xvi. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of waiting time;
xvii. Next, to ABO identical ~~patients~~candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
xviii. Next, to ABO compatible ~~patients~~candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;
xix. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of waiting time; and
xx. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of waiting time.

3.7.11.1 Sequence of Pediatric Donor Lung Allocation. Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, and finally, to candidates in Zone D. In each of those five geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for lungs from donors 0 – 11 years old is as follows:

i. First locally to ABO identical candidates 0 – 11 years old according to length of time waiting;
ii. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;
iii. Next, locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
iv. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
v. Next, locally to ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
vi. Next, locally to ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;
viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;
ix. Next, to ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
x. Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;
xi. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xii. Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xiii. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;
xiv. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;
xv. Next, to ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
xvi. Next, to ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;
xvii. Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
xviii. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
xix. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of time waiting;

xx. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of time waiting;
xxi. Next, to ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
xxii. Next, to ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;
xxiii Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
xxiv. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
xxv. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of time waiting;
xxvi. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of time waiting;
xxvii. Next, to ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
xxviii. Next, to ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;
xxix. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
xxx. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidates age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, and finally, to candidates in Zone D. In each of those five geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor. In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

i. First locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
ii. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
iii. Next, locally to ABO identical candidates 0 – 11 years old according to length of time waiting;
iv. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;
v. Next, locally to ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;
vi. Next, locally to ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;
vii. Next, to ABO identical candidates 12 – 17 years old in zone A according to Lung Allocation Score in descending order;
viii. Next, to ABO compatible candidates 12 – 17 years old in zone A according to Lung Allocation Score in descending order;
ix. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;

x. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;
xi. Next, to ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xii. Next, to ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;
xiii. Next, to ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
xiv. Next, to ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;
xv. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;
xvi. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;
xvii. Next, to ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
xviii. Next, to ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;
xix. Next, to ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
xx. Next, to ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;
xxi. Next, to ABO identical candidates 0 – 11 years old in Zone C according to length of time waiting;
xxii. Next, to ABO compatible candidates 0 – 11 years old in Zone C according to length of time waiting;
xxiii. Next, to ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;
xxiv. Next, to ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;
xxv. Next, to ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
xxvi. Next, to ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;
xxvii. Next, to ABO identical candidates 0 – 11 years old in Zone D according to length of time waiting;
xxviii. Next, to ABO compatible candidates 0 – 11 years old in Zone D according to length of time waiting;
xxix. Next, to ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and
xxx. Next, to ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

(NO FURTHER CHANGES TO POLICY 3.7.6, POLICY 3.7.9, POLICY 3.7.9.2, AND POLICY 3.7.11)

Attachment A

Patient Lung Data Variables to be Collected

It is the intent of the OPTN/UNOS Lung Allocation Subcommittee to collect the following data from the medical records of selected lung transplant patients on the waitlist. All pulmonary function tests and heart catheterization data are to be collected from the time of listing through the date of the most recent available tests, including the time of transplant, if applicable. All other data is to be collected at the time of listing, and at the date of the most recent available responses, including the time of transplant, if applicable. If, in the event serial data is available for these remaining categories, data is to be collected at the time of listing, at six-month intervals thereafter through the date of the most recent responses, including the date of transplant, if applicable.

(* indicates data not currently reported to the OPTN at the time of listing)

Basic:

Age
Height
Weight
*Hematocrit and Hemoglobin

Arterial Blood Gases:

$PaCO_2$
*PaO_2
*Oxygen saturation

Severity of Illness:

6-Minute walk distance with report of O_2 used

Ventilation: (Collect and date all PFT's from the date of listing through the date of the most current test, or the time of transplant, if applicable)

FVC (absolute and % predicted)
Post-bronchodilator FEV_1 (absolute and % predicted)
*TLC (absolute and % predicted)
*FEF_{25-75} (absolute and % predicted)
*Peak Expiratory Flow *
*Lung Residual Volume *

(These items were added, following the May 9, 2003, meeting, at the suggestion of Michael Krowka, MD. He noted that these two measures of pulmonary function combined with FEV_1 are a more complete indicator of the severity of COPD than FEV1 alone.)

*DLCO (absolute and % predicted)

Blood Flow: (Collect and date all PFT's from the date of listing through the date of the most current test, or the time of transplant, if applicable)

Cardiac output (cardiac catheterization, echocardiography, radionuclide scintigraphy)
Pulmonary artery pressure (mean, systolic, and diastolic)

*Pulmonary vascular resistance
*Right ventricle ejection fraction
*Left ventricle ejection fraction (echocardiography)
*Tricuspid regurgitation (cardiac catheterization, echocardiography)

Physiologic Reserve:

Right Heart Dysfunction:

*Right atrial pressure / central venous pressure
*Bilirubin
*Serum glutamate oxaloacetate transaminase (SGOT)
*Serum glutamate pyruvate transaminase (SGPT)
*INR
Albumin
*Evidence of ascites

Other Organ System Dysfunction:

*Evidence of arrhythmia (atrial, block, ventricular)
Evidence of angina
Serum Creatinine
New York Heart Association class (functional capacity)
*Admissions to hospital *(Collect all dates and reasons for readmission from the date of listing through the present- ICD-9-CM code)*
Evidence of diabetes
*History or cerebral vascular disease (CVA and TIA, separately)
History of peripheral vascular disease

Disease Specific Data Elements:

Group IPF:

*Pathologic Diagnosis (desquamative interstitial pneumonitis [DIP] vs. usual interstitial pneumonitis [UIP])

Group CF:

*Lung organism microbiology (dates and types)
*Evidence of pancreatic insufficiency

Donor Organ Viability and Suitability:

Data to be obtained from the Deceased Donor Registration form – no new data.