OPTN/UNOS
THORACIC ORGAN TRANSPLANTATION COMMITTEE
SUMMARY
June 24-25, 2005

I. Organ Availability Issues

Action Items for Board Consideration

- The Board is asked to approve modifications to 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). (Item 1, Page 1)

- The Board is asked to approve a thoracic organ alternative distribution system request from LifeCenter NorthWest (WALC). (Item 5, Page 13)

- The Board is asked to approve a thoracic organ alternative distribution system request from Organ Donor Center of Hawaii (HIOP). (Item 6, Page 13)

Other Significant Items

- None

II. Patient Access Issues:

Action Items for Board Consideration

- The Board is asked to approve eight requests for thoracic organ waiting time modification. (Item 11, Page 20)

Other Significant Items

- None

III. Other Issues

Action Items for Board Consideration

- The Board is asked to approve resolutions to contact OPO's with heart recovery and use data as part of a project to study data and recommend ways to improve heart recovery and use rates. (Item 7, Page 14)

- The Board is asked to approve resolutions to contact OPO's with lung recovery and use data as part of a project to study data and recommend ways to improve lung recovery and use rates. (Item 8, Page 16)

- The Board is asked to approve a resolution for the Thoracic Committee to meet with Executive Committee to discuss the passage of a lung sharing agreement in Region 6 at the November 21-22, 2003, Board of Directors meeting. (Item 10, Page 18)

Other Significant Items

- The Committee continued work on drafting statements of thoracic organ allocation policy goals and performance indicators as found in the Final Rule. (Item 2, Page 12)

- The Committee reviewed a presentation by the Data Working Group on a pilot project to study additional transplant endpoints. (Item 9, Page 18)

- The Heart Subcommittee requested data to assist it in reviewing allocation policies at they apply to patients implanted with VAD's. (Item 3, Page 12)

- The Committee considered a request to expand the information required to be entered with Heart Status 1A listings. (Item 14, Page 13)

- The Committee responded to a request from the OPO Committee to offer recommendations on proposals by that committee. (Item 12, Page 21)

- The Committee reviewed a UK model of predicting individual survival in kidney patients. (Item 13, Page 21)

Report of the OPTN/ UNOS Thoracic Organ Transplantation Committee to the Board of Directors June 24-25, 2004 Minneapolis, Minnesota

O. Howard Frazier, M.D., Chairman
Edward R. Garrity, Jr., M.D., Vice-Chairman

The following report presents the OPTN/UNOS Thoracic Organ Transplantation Committee's deliberations and recommendations on matters considered by the Committee during its January 23, 2004, and May 14, 2004, meetings.

1. Review and Approval of Amendments to 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)

Since the November 21, 2003, meeting of the OPTN/UNOS Board of Directors, the Thoracic Committee, based on the work of the Lung Subcommittee, has extensively reviewed and discussed the proposed modifications to the existing lung allocation system. A full account of the history of development of the lung allocation system can be found in the attached Briefing Paper (**Exhibit A**).

Following the presentation of the revised lung allocation system at the November 21, 2003, Board of Directors meeting, the Joint Pediatric/Lung Subcommittee met on December 3, 2003, to discuss the implications of the revised lung model for pediatric and adolescent lung candidates. At this meeting, the members agreed to request further statistical modeling to determine whether survival advantages exist for candidates under 18 who are transplanted with lungs from donors under 18 yeas old rather than lungs from adult donors.

The Lung Subcommittee met in person on January 23, 2004, to finalize revisions to the lung allocation system proposal. At this meeting, the Subcommittee voted to submit revised policy changes to the lung allocation system that was presented to the Board of Directors in November 2003, for public comment. The Thoracic Committee concurred with the Lung Subcommittee's revisions. The allocation proposal was released for public comment on March 25, 2004, and offered the following features:

- **Waitlist Urgency vs. Transplant Benefit**. 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**. 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.

- **Clinical diagnostic values.** 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.

- **Lung Allocation Score.** Each candidate will receive a Lung Allocation Score on a 0-100 point scale. Patients will be prioritized for lung offers based on the Lung Allocation Score they receive in descending order.

- **Pediatric transplant candidates.** 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.

- **Adolescent transplant candidates.** 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.

- **Survival data.** Survival data, around which the algorithm is based, should use a **3-year cohort of patients**, and that this survival cohort should be updated each year to reflect changes in survival rates among transplant candidates and recipients.

- **Updating candidate variables.** Transplant centers may update their candidates' diagnostic information **at any time** to reflect the most current severity of their illnesses. Transplant centers, however, would be **required** to update their variables **at a regular interval established by the Committee** to preserve the accuracy of the system.

- **Implementation.** Transplant centers will be notified of policy modifications and will receive six months' notice prior to the implementation of the system to enter their candidates' diagnostic variables onto the system. Patients currently registered on the UNOS waitlist at the time of implementation with no data or incomplete data will receive a Lung Allocation Score of zero, giving them the lowest priority until their data is entered. Patients with 0 scores will receive priority among each other based on ABO and accrued wait time.

- **Candidates with incomplete data**. Candidates added to the waitlist after implementation of the system with no diagnostic data will receive a Lung Allocation Score of zero. Patients with incomplete data will receive a default value for each incomplete data field. The default value will be calculated to result in the lowest contribution to the Lung Allocation Score for that variable.

- **Candidate data unobtainable**. Where a required test to gather diagnostic data cannot be safely performed on a candidate, the transplant center may enter an override value for that variable field. Override values will be reviewed by the Thoracic Committee to determine appropriateness.

- **Review and revision.** The Thoracic Committee will continually revise and improve the lung allocation system through periodic data analysis of updated patient populations. Factors determined to be important predictors of waitlist mortality and post-transplant survival are listed in Tables 1 and 2 of the proposed policy. It is expected that these factors will change over time as new data are available and added to the models. The Committee will review these data in regular intervals of approximately six months and will update the factors used to predict the risk of death on the lung waiting list and the factors used to predict survival after a lung transplant. Modifications to these factors will be reported to the OPTN/UNOS Board of Directors on a retrospective basis.

On May 14, 2004, the Lung Subcommittee and Thoracic Committee reviewed the public comment responses. As of May 9, 2004, 199 responses were submitted to UNOS regarding this policy proposal. Of these, 147 (73.87%) supported the proposal, 42 (21.11%) opposed the proposal, and 10 (5.03%) had no opinion. Of the 189 who responded with an opinion, 147 (77.78%) supported the proposal and 42 (22.22%) opposed the proposal **(Exhibit B**). The proposal was reviewed by the Regions and received overall support in 9 of 11 Regions. (**Exhibit C**).

Revisions and the Final Proposal. At the May 14, 2004, meeting the Lung Subcommittee and Thoracic Committee discussed final revisions to be made to the lung system proposal based on responses to public comment.

- **Recertification Schedule.** The Committee first considered the recertification schedule under which transplant centers would be required to update candidates' clinical variables. The Committee noted that although it specifically asked for public comment on this issue, it received very little response. In its initial discussion of this issue, the Lung Subcommittee had considered a six-month recertification schedule for data that may be acquired through non-invasive tests. This suggestion was brought to the attention of the full Thoracic Committee, which noted that the heart catheterizations carried a level of risk to the candidate. The Committee then unanimously agreed that the lung proposal should be revised to require six-month certification of all data variables except those that must be obtained by a heart catheterization (PA systolic, PCW pressure). Recertification of those variables would be left to the discretion of the transplant center.

- **Prospective Data Collection.** Reviewing and revision of the lung allocation system to evaluate the effectiveness of the system and reflect changes in patient survival trends are major components of the proposal. The Committee has maintained that the optimal way to do this is through the collection of patient data. The Committee sanctioned the collection of retrospective data from a selected cohort of patients listed at transplant centers around the country. This retrospective data collection project was completed in March 2004, and, and the data is currently being analyzed by SRTR. Following extensive discussion at the May 14, 2004, meeting, the Committee agreed that it would wait for the results of this data analysis before making a decision as to what data variables would be required to be collected from patients in the future. At this time, the Committee agreed that UNet would collect data from patients that is necessary for the operation of the lung allocation system. If review of the data reveals that additional data may be helpful to the operation of the system, then the Committee would propose the ongoing collection of those particular data variables on the UNet system.

- **Exceptional Case Review.** Lung Subcommittee and the Thoracic Committee agreed that a review process may be necessary to review unique situations where patients are not served by the system as intended. The group agreed that the establishment of a **Lung Regional Review Board** would be a way to give patients and clinicians an avenue to pursue when they believe that a patient may fall outside the goals of the system. The Subcommittee agreed to incorporate general provisions into the proposed policy changes to establish a Lung RRB to review exceptional cases. Members agreed to create the review mechanism, but to organize the RRB and set case review time limits and guidelines in future meetings prior to implementation of the system. The specific policy provisions for the Lung RRB will be submitted for approval by the Board of Directors.

- **Future Actions by the Thoracic Committee.** The Lung Subcommittee also recommended to the Thoracic Committee that it host a national forum, after the lung allocation system has been in operation for a period of time, to collect responses and feedback from transplant centers concerning the effectiveness of the system.

Following the discussion, the Thoracic Committee voted unanimously to recommend the following resolution for consideration by the Board:

****RESOLVED, that the proposed policy modifications having been circulated for public comment, and reconsidered by the OPTN/UNOS Thoracic Organ Transplantation Committee, the amended language proposed below as 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) is hereby approved and shall be implemented upon completion of programming in the UNOS system.**

3.7.6 **~~Status of Patients Awaiting~~ Lung Allocation.~~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[1])
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

[1] **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. Programs must update every candidate variable, except those candidate variables that are obtainable only by heart catheterization, for each candidate at least once every six months beginning on the date of initial listing on the lung waitlist. The frequency of updating those candidate variables that are obtainable only by heart catheterization will be left to the discretion of the transplant center.

3.7.6.4 Lung Candidates With Exceptional Cases. Special cases require review by the Lung Regional Review Board. The transplant center will accompany each request for special case review with a supporting narrative. The Thoracic Committee shall establish guidelines for special case review by the Lung RRB's.

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)

2. OPTN Policy Development and the Final Rule – At the January 23, 2004, meeting, the Committee considered the resolution passed by the Board of Directors at the June 20, 2003, meeting requiring organ allocation committees to specifically address the performance goals and indicators found in the Final Rule **(Exhibit D)**. The Thoracic Committee recommended that UNOS staff draft appropriate language for the Committee to review at its May 2004 meeting.

At the May 14, 2004, meeting, the Thoracic Committee reviewed draft language that addressed the performance goals of the heart allocation policies and the proposed lung allocation policies (**Exhibit E**). The Thoracic Committee discussed the issue, and it was noted that increased organ utilization should be among the goals. The Committee did not reach an agreement on the proposed policy language, but agreed to refer the issue back to the Heart and Lung Subcommittees for further review to draft additional language, if necessary, to be reviewed by the Committee at its next meeting.

3. Report of the Heart Allocation Subcommittee. At the January 23, 2004, meeting, the Heart Subcommittee continued its refinement of the of the online Status 1A justification forms. The Subcommittee reviewed the specification documents for the on-line Status 1A(d) forms and approved the following minimum and maximum acceptable ranges for the following:

IV Nitroglycerine: 0.05-10 mcg/kg/min
Nesiritide (Natrecor): 0.005 - .05 mcg/kg/min
Nitroprusside: 0/05 – 10 mcg/kg/min

A value entered outside the indicated ranges will display a prompt for the user to confirm that the value they entered is valid. This should reduce erroneous data caused by typographical errors but also allow for unusual cases where the value does exceed the indicated therapeutic range.

The Subcommittee was notified that programming on the UNet system is almost complete, and is expected to be implemented in fall of 2004. The Subcommittee noted that it would be preferable to provide at least 60 days notice to program directors, coordinators, and surgical directors prior to the implementation of the on-line status justification system.

Further, the Subcommittee suggested that on-line justification forms for Status 1A Exceptions should be completed entirely for patients to be listed at that status. The Subcommittee advised that unless all data fields are completely filled in, a center should not be allowed to list it's patient. This is not suggested as a punitive measure, but rather a method to ensure that the on-line system is functioning properly and that the Regional Review Boards are receiving complete data on each patient. If a patient's hemodynamic values are not obtainable, the listing center should be required to indicate that the values are unobtainable, and then specify a reason why those values are not obtainable. The Committee also suggested that ejection fraction values would be filled in on the initial listing, and should not require updating for Status 1A extensions. The Subcommittee also advised that lab values should be updated within 24 hours of Status 1A(d) and 1A Exception listings or extensions.

The Heart Subcommittee selected a small group to consult with UNOS programmers on future technical programming issues so that these would not have to wait to be brought before the full Subcommittee. This group will consist of : W. Steves Ring, MD, J. David Vega, MD, Jeffrey D. Hosenpud, MD, and R. Douglas Ensley, MD. At this meeting, the Heart Subcommittee also nominated new Subcommittee members. Those are: W. Steves Ring, MD, Chair, Jeffrey D. Hosenpud, MD, J. David Vega, MD, Wayne E. Richenbacher, MD, R. Douglas Ensley, MD, Wayne D. Babcock, RN, CPTC, Charles C. Canver, MD, and O. Howard Frazier, MD.

The Subcommittee discussed the issue of establishing minimum dosages for the low dose inotropes required for Status 1A(d) listing. This was at the request of a member in Region 3 who expressed concern that this requirement leaves a great deal of latitude for abuse by centers who would list patients at a nominal dosage of inotrope simply to justify a Status 1A(d) listing. The Subcommittee agreed to examine the data collected by the on-line justification forms, and then revisit the issue to determine if action needs to be taken.

The Subcommittee examined data produced by UNOS on VAD use among adult heart waitlist candidates and transplant recipients. (**Exhibit F**). The data was produced in response to past committee discussion that considered a change 30-day time limit found in Status 1A(a). The data tabulated the time since VAD implantation for waitlist candidates and recipients. The Committee found the information useful, but decided that it could be expanded by producing a similar table of data that separated the candidates by type or brand of VAD device. The full Committee later visited this issue along with a data presentation from SRTR **(Exhibit G).** Following a lengthy discussion, the Committee agreed to examine the data and research request by the Heart Subcommittee, and both groups will revisit this issue at a future meeting. This issue was addressed again on a conference call with the Heart Subcommittee on April 9, 2004, in which the Subcommittee clarified what data it wanted to collect and analyze. Although the analysis data was included in materials distributed for the May 14, 2004, Thoracic Committee meeting, time limitations prevented the Committee from addressing this issue at that meeting. It will be reviewed at future meetings.

4. Gathering Additional Information for Status 1A Listings – At the January 23, 2004, meeting, the Committee examined a request from doctors in Region 2 who asked that the Committee consider a proposal to require centers to offer additional information prior to listing patients as Status 1A. Doubts were expressed from this Region regarding the veracity and completeness of Status 1A applications. The Committee agreed to gather additional information from the on-line justification forms and revisit the issue at a later meeting.

5. Alternative Distribution System Request from LifeCenter NorthWest (WALC) At the January 23, 2004, meeting, Lynn Cravero, Director of Clinical Services at LifeCenter NorthWest (WALC) presented an alternative distribution system request for Committee approval **(Exhibit H)**. WALC noted that in past years, it has been necessary to offer organs from Alaska donors to Canadian transplant centers because the Canadian centers were closer to WALC than the nearest eligible US recipient. Ms. Cravero noted that in 2003, WALC allocated one heart and two lungs to Canadian centers due to these circumstances. In each case, she notes, WALC has made offers to Canadian centers only after U.S. donor match runs have been exhausted and time and/or distance are the only refusal reasons given. In every case, WALC has notified UNOS of its intention to contact Canadian centers with organ offers, and has informed UNOS immediately whenever the organ has been accepted.

Following a brief discussion, the Committee voted and unanimously agreed to recommend approval of an alternative distribution system for WALC in which it would offer thoracic organs where the donor is from Alaska through the end of Zone C before making offers to closer Canadian transplant centers.

> ****RESOLVED, that the thoracic organ alternative distribution system requested by LifeCenter Northwest, whereby it would offer thoracic organs, where the donor is from Alaska, through the end of Zone C prior to making offers to closer transplant centers in Canada, be implemented and effective upon approval by the Board of Directors and programming in the UNOS system.**

6. Proposed Addition of Allocation Zone for Hawaii – At the January 23, 2004, meeting, Organ Donor Center of Hawaii (HIOP) presented a proposal **(Exhibit I)** for an alternative distribution system that would modify the thoracic allocation zone system for Hawaii donors by establishing Zones X and Y for the allocation of thoracic organs. Thoracic organs from Hawaii donors would be offered first

locally, and then to Zone X which would extend to all transplant centers within 2,500 miles of Honolulu, and then to Zone Y which would extend to all centers that are beyond 2,500 miles of Honolulu. Christopher Carroll, RN, CPTC, of HIOP presented information that the extreme distance from the mainland makes placing thoracic organs outside the HIOP local area extremely difficult in that the entire mainland United States falls within Zone D. Therefore, the entire US candidate list appears in match runs, and it is left to HIOP to eliminate those candidates that fall outside the feasible range of cold ischemia and travel time. Each time, these patients are "bypassed," HIOP must submit an explanation to UNOS Policy Compliance. HIOP noted that this proposed system would create more realistic match runs, and include only those candidates that are within the acceptable range of cold ischemic time and distance while excluding those who are outside these functional limits.

The Committee considered HIOP's proposal and after discussion, voted unanimously to recommend approval of the proposed thoracic organ alternative distribution system for Hawaii.

****RESOLVED, that the thoracic organ alternative distribution system requested by Organ Donor Center of Hawaii, as presented in Exhibit I, whereby thoracic organs from Hawaii donors would be offered first locally, and then to Zone X which would extend to all transplant centers within 2,500 miles of Honolulu, and then to Zone Y which would extend to all centers that are beyond 2,500 miles of Honolulu, be implemented and effective upon approval by the Board of Directors and programming in the UNOS system.**

7. Update of the Heart Recovery and Use Subcommittee and Proposals.– At the October 3, 2003, meeting, the Thoracic Committee formed the Heart Recovery and Use Subcommittee to study heart recovery and placement trends and recommend ways to improve the number of hearts transplanted. Subcommittee members met for the first time by teleconference on December 17, 2003. At this meeting, the Subcommittee began the task of studying heart recovery data and heart use data for OPO's throughout the OPTN to recommend improvements to heart recovery and transplantation rates. The Subcommittee began by examining UNOS data collected between January 1, 2002, and June 30, 2003, on the transplant rate, by OPO for donors for whom consent for heart recovery was obtained. This was limited to brain dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). The data indicated that there were 4885 donors recovered, and of these donors 2342 (48%) were transplanted. Of the 2543 donors in who the heart was not transplanted, there was approximately an equal distribution between the following four groups" heart match not run, match was run but offer efforts not reported, only local offers made, and offers made to Zone A and beyond **(Exhibit J-5)**.

Following the presentation of the data, the Subcommittee determined that the data presented may not show the full scope of heart use, and that a more accurate picture of heart use may shown by obtaining the function data for the organs recovered. The Subcommittee noted that organ function data may demonstrate why organs are not being transplanted. The Subcommittee requested additional data concerning the medical and social characteristics of donor for whom no match was run. The Subcommittee agreed to examine this data at its next meeting.

The Subcommittee also discussed ideas for streamlining the listing process such that offers may be made more efficiently to expedite the organ placement process. Suggestions included narrowing the acceptance age range, and utilizing the distance range that centers indicate they are willing to travel to recover an organ. The Subcommittee agreed to revisit this issue at its next meeting and offer further suggestions to streamline the process.

At the January 23, 2004, meeting, the Subcommittee updated the full Thoracic Committee on its findings. Following a brief discussion, the Committee agreed unanimously that the Subcommittee should examine the additional data it requested, and return to the Thoracic Committee in May 2004 with policy proposals to improve organ usage.

The Heart Recovery and Use Subcommittee met again by teleconference April 15, 2004. At this meeting the Subcommittee examined UNOS data collected between January 1, 2002, and June 30, 2003, on the transplant rate, by OPO for donors for whom consent for heart recovery was obtained. This was limited to brain dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). The data indicated that there were 4885 donors recovered, and of these donors 2342 (48%) were transplanted. Of the 2543 donors in who the heart was not transplanted, there was approximately an equal distribution between the following four groups: heart match not run, match was run but offer efforts not reported, only local offers made, and offers made to Zone A and beyond. The Subcommittee expressed particular concern that of the donors not transplanted, 587 (23%) had no match run. The Committee then examined data, from January 1, 2002, through June 30, 2003, broken down by OPO, detailing the number of donors consented, donors not transplanted, and donors transplanted. The data also indicated, by OPO, the number of transplants within the local area, and outside the OPO **(Exhibit J-8 – J-10)**.

Following the presentation of the data, the Subcommittee suggested that a first step to increasing heart usage would be to understand the reason why such a significant percent of hearts from recovered donors do not have a match run made. To understand the reasons for this, the Subcommittee suggested the following actions:

- Producing a questionnaire for OPO's to complete a questionnaire regarding offering practices to determine:
  1. Age at which no match will be run and no offer is made outside the local OPO
  2. Is echo performed in cases where no match is run
  3. Any specific indicators that would immediately exclude a donor heart from a match run
  4. An outline of practices to determine what circumstances will lead to a match run and what factors will exclude a heart from match run

- Auditing a random sample of 10% of the cases where heart matches were not run to determine reasons for not running a match on those hearts. It was suggested that Regional Representatives personally contact those OPO's within their regions to learn the details surrounding those instances where a heart match is not run and no offers were made outside the local area.

At the May 14, 2004, meeting Thoracic Committee members considered the Subcommittee's recommendations. One member proposed a resolution that OPO's be required to run at least one match on every donor heart procured. This member believed that an increase in the numbers of offers, would lead to an increase in transplantation. This motion was withdrawn when it was suggested by another member that some hearts may have absolute contraindications to transplantation, and that it may be overly burdensome on OPO's to match each and every heart despite obvious contraindications to transplantation. Another member suggested the creation of an online "clearing house" where OPO's may offer hearts nationally that were turned down after a specified number of offers. It was also suggested that the Thoracic Committee further narrow the donor acceptance criteria that centers may enter on UNet. At the close of the discussion, the Heart Use Subcommittee was asked to meet again to determine a list of donor organ factors that would be considered absolute contraindications to accepting a donor heart.

Following the discussion, the Thoracic Committee voted and unanimously agreed to propose the following resolution for approval by the Board of Directors:

**** RESOLVED, that the Thoracic Committee provide specific data to each OPO to show its heart recovery and use rates in comparison to other OPO's nationwide, with the intent of opening a dialogue between centers and OPO's to discuss ways to increase recovery and use within that OPO, and provide a questionnaire to the OPO's addressing the following four points:**

1. **Age at which no match will be run and no offer is made outside the local OPO?**
2. **Is echo performed in cases where no match is run?**
3. **Any specific indicators that would immediately exclude a donor heart from a match run.**
4. **An outline of practices to determine what circumstances will lead to a match run and what factors will exclude a heart from match run.**

****FURTHER RESOLVED, that the Thoracic Committee review a random sample of 10% of all the cases nationally where a heart match was not run and contact the appropriate OPO's to learn the reason no match was run in each case.**

8. Update of the Lung Recovery and Use Subcommittee and Proposals. At the October 3, 2003, meeting, the Thoracic Committee formed Lung Recovery and Use Subcommittee to study lung recovery and placement trends and recommend ways to improve the number of lungs transplanted. Subcommittee members met for the first time by teleconference on December 16, 2003. At this meeting, the Subcommittee began the task of studying lung recovery data and lung use data for OPO's throughout the OPTN to recommend improvements to lung recovery and transplantation rates. The Subcommittee began by examining UNOS data collected between January 1, 2002, and June 30, 2003, on the transplant rate, by OPO for donors for whom consent for lung recovery was obtained. **(Exhibit K-5)**. This was limited to brain dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). The data indicated that there were 4786 donors recovered, and of these donors at least one lung was transplanted in 1015 (21%). From these donors, 1219 lung transplants were performed involving 1810 lungs. Of the 3771 (79%) donors in whom the lung was not transplanted, there was approximately an equal distribution between the following four groups: lung match not run, match was run but offer efforts not reported, only local offers made, and offers made to Zone A and beyond.

Following the presentation of the data, the Subcommittee noted that to fully appreciate the national recovery and use rates, it would be advantageous to be aware of the performance data on the lungs that are not placed. The Subcommittee specifically requested information on PO_2 data, smoking history, and cause of death. It was suggested that donor lungs where PO_2 is less than 250 should not be transplanted. The Subcommittee suggested that it should take a closer look at instances where lungs with a $PO_2 > 250$ are not offered or placed. The Subcommittee also requested to study difference between placement rates in OPO's that have lung transplant centers within them and those that do not. The Subcommittee concluded that it would review the additional data at a later meeting.

The Subcommittee also discussed ideas for streamlining the listing process such that offers may be made more efficiently to expedite the organ placement process. Suggestions included narrowing the acceptance age range, narrowing the size and weight range, and utilizing the distance range that centers indicate they are willing to travel to recover an organ. The Subcommittee agreed to revisit this issue at its next meeting and offer further suggestions to streamline the process.

The Subcommittee also noted that one of its goals should be to notify OPO know where it ranks nationally in relation to other OPO's in organ recovery and use **(Exhibit K-11)**. The Subcommittee notes that this is a step toward improving the production of those OPO's that fall below the national average. It was suggested that the OPO's with the highest placement rates should be contacted to learn management strategies, so that these can be applied to other centers to improve their placement rates.

At the January 23, 2004, meeting, the Subcommittee updated the full Thoracic Committee on its findings. Following a discussion, the full Committee agreed with the Subcommittee that the amount of information collected was not sufficient to fully understand the high turndown rates. The Committee unanimously resolved that the Subcommittee request from OPO's on each lung where no match is run or the lung is not placed, the first and last PO_2 challenge, the most recent chest X-ray, and a

justification for any turndowns by transplant centers. The Committee further agreed unanimously that the Subcommittee should examine the additional data it requested, and return to the Thoracic Committee in May 2004 with policy proposals to improve organ usage.

The Lung Recovery and Use Subcommittee met again by teleconference April 16, 2004. At this meeting, the Subcommittee began by examining UNOS data collected between January 1, 2002, and June 30, 2003, on the transplant rate, by OPO for donors for whom consent for lung recovery was obtained. This was limited to brain dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). The data indicated that there were 4786 donors recovered, and of these donors at least one lung was transplanted in 1015 (21%). From these donors, 1219 lung transplants were performed involving 1810 lungs. Of the 3771 (79%) donors in whom the lung was not transplanted, there was approximately an equal distribution between the following four groups: lung match not run, match was run but offer efforts not reported, only local offers made, and offers made to Zone A and beyond. The Subcommittee expressed particular concern that of the donors not transplanted, 1085 (29%) had no match run.

The Subcommittee suggested that additional function data is needed on donor lungs, and the Subcommittee noted that this need for more function data will be met in June 2005 by revisions to the DDR to gather pulmonary function data, final PO2 levels, chest radiograph results.

Following the presentation of the data, the Subcommittee had the following suggestions for actions to be taken by the Thoracic Committee:

1. Providing specific data to each OPO to show its recovery and use rates in comparison to other OPO's nationwide. This data would also be provided to the transplant centers to open a dialogue between centers and OPO's to discuss ways to increase recovery and use within that OPO **(Exhibit K-8 – K10)**.

2. Voluntary review by the Thoracic Committee of OPO's with low use levels that deviate from the national average. This would allow the Committee to understand why low use levels are occurring and suggest practices to increase donor use. It was suggested that the Thoracic Committee cooperate with AOPO in carrying out this project.

3. Conducting a regional-based pilot study for comparison of donor management practices between high and low performers. A regional-based comparison based on specific performance outcomes would allow the entire community to better assess variations in donor management.

4. A statement from Thoracic Committee to encourage direct lung offers from procuring OPO's to transplant center staff (eliminate host OPO receiving lung offers). This request may be supplemented with a questionnaire to OPO's to determine their preference.

5. Program the UNet screen-off to match the distance parameter with the maximum distance that the transplant center indicates it will accept.

At the May 14, 2004, meeting Thoracic Committee members considered the Subcommittee's recommendations. One member proposed a resolution that OPO's be required to run at least one match on every donor lung procured. This member believed that an increase in the numbers of offers, would lead to an increase in transplantation. This motion was withdrawn when another member suggested that more effective strategy to improving the number of lungs transplanted would be to evaluate donor management practices among OPO's and work to improve them to maximize outcomes. It was also suggested that the Thoracic Committee further narrow the lung donor acceptance criteria that centers may enter on UNet.

Following the discussion, the Thoracic Committee voted and unanimously agreed to propose the following resolution for approval by the Board of Directors:

> ****RESOLVED, that the Thoracic Committee provide specific data to each OPO to show its lung use rates in comparison to other OPO's nationwide with the intent of opening a dialogue between centers and OPO's to discuss ways to increase recovery and use within that OPO.**
>
> ****FURTHER RESOLVED, that the Thoracic Committee conduct a voluntary review OPO's with lung transplant rates less than 15%, excluding those in Hawaii and Puerto Rico, to help the Committee learn why low use levels are occurring and suggest practices to increase donor use.**
>
> ****FURTHER RESOLVED, that the Thoracic Committee conduct a regional-based pilot study for comparison of donor lung management practices between high and low performers with the intent of allowing the entire community to better assess variations in donor management.**

9. Review of Data Working Group Additional Transplant Endpoints. At the May 14, 2004, meeting, Dr. Larry Hunsicker appeared on behalf of the OPTN/SRTR Data Working Group to update the Thoracic Committee on that group's pilot study of additional transplant outcomes **(Exhibit L)**. The DWG has identified major categories of additional transplant endpoints that may useful in evaluating the role of transplantation in decreasing patient morbidity and burden of disease, thereby improving patient quality of life and functional status. The DWG proposed a pilot study to collect functional status and quality of life data directly from patients by conducting a survey of a randomly selected cohort of patients using a health related quality-of-life questionnaire. It is anticipated that the study will be completed in three years.

Following the presentation, Thoracic Committee members cautioned that differences among treatments and outcomes at transplant centers may have a biasing effect on the data collected by the study. The Committee agreed to provide the DWG with input as the study progresses.

10. Region 6 Sharing Agreement Revisited – At the May 16, 2003, meeting, Region 6 presented a proposal to form a lung sharing agreement. The proposed sharing agreement would consolidate the lung waiting lists of Pacific Northwest Transplant Bank (PNTB) and LifeCenter Northwest (LCNW) into one common local lung waiting list. The parties to the agreement presented the Thoracic Committee with a signed copy of the sharing agreement for its review. The parties to the agreement requested that the Thoracic Committee recommend approval to the Board of Directors.

The Committee in discussing the proposed sharing agreement, noted that the sharing agreement would include all of Washington and Oregon. The Committee also recognized that the sharing agreement, if approved, would have the effect of keeping a great majority of lungs procured there within those two states and offering them almost exclusively to the lung transplant center at the University of Washington Medical Center (UWMC). The Committee believed that the sharing agreement, if approved, would have a detrimental effect on lung placement at transplant centers that are within a 500-mile radius of Region 6. It was believed that those centers would no longer receive offers from Region 6, because those offers would then be made within the boundaries of Oregon and Washington.

After the presentation of data from Region 6, discussion, and debate, the Thoracic Committee declined to approve the Region 6 sharing agreement.

At the October 3, 2003, meeting, the parties to the lung sharing agreement requested that the Committee reconsider their request. Douglas E. Wood, M.D., Michael S. Mulligan, M.D., Michael Seely, and Monica Johnson-Tomanka appeared on behalf of the parties with a slide presentation of data to support the proposed sharing agreement. The applicants' proposed sharing agreement would

define all of Region 6, except Hawaii, as "local" for the purposes of lung allocation. It was noted that the proposed agreement has the approval of PNTB, LCNW, Region 6, and all five Region 6 thoracic transplant programs. The applicants also noted that the proposed agreement improves the relationship of the OPO's with the lung transplant center, helps to avoid organ loss, improves OPO efficiency, and potentially improves patient outcomes. The applicants submit that the geography of Region 6 and the relative isolation of UWMC in relation to other transplant centers set this region apart, in that the proposed sharing agreement will have a minimal impact on offers to the nearest centers in Zone A: University of Utah, UC-San Francisco, University of Colorado, and Stanford.

During the discussion, several members of the Committee were concerned that the proposed sharing agreement was substantially different from others that the Committee had previously approved in that it combined the resources of two states, rather than one single state. Additionally, members of the Committee expressed concern that the practical effect of the proposed sharing agreement would be to direct almost all organs procured in Oregon to UWMC, and deprive transplant centers in Zone A and primarily in Northern California of organ offers that they would otherwise receive. One member of the Committee opined that the agreement should be approved since all parties involved in Oregon and Washington have consented. However, other members of the Committee responded by noting that, although the parties directly involved are in agreement, the others centers that will be indirectly affected have not consented to the proposed agreement.

After extended discussion, the Committee was unconvinced that the proposed lung sharing agreement in Region 6 would be more beneficial to the Region or surrounding areas than the current system. By vote, in which Committee members whose centers or regions may potentially be affected by the implementation of the proposed sharing agreement abstained from voting, the Committee declined to approve the sharing agreement proposed by the parties in Region 6.

At the November 20, 2003, OPTN/UNOS Board of Directors meeting, a resolution to approve the Region 6 lung sharing agreement was presented to the Board based on discussions by the Executive Committee. A presentation by Doug Wood, M.D. to the Executive Committee provided additional information regarding agreement by the lung transplant programs at Stanford, University of California-San Francisco and the University of Utah. The Board of Directors voted to approve the Region 6 lung variance.

At the January 23, 2004, meeting Thoracic Committee several members expressed concern that the Board of Directors approved this sharing agreement when the Committee had recommended not to approve it. The members requested that the additional information that was presented be made available to them at the next Committee meeting. Those members also requested that the applicable sections of the Board meeting minutes be available to them at the next Committee meeting so that they may understand the rationale of the Board in approving the application.

The transcript of the applicable portion of the November 21, 2004, Board of Directors meeting was provided to the Thoracic Committee at the May 14, 2004, meeting. The Committee discussed the issue and reiterated its concern that the Board approved a sharing agreement that the Committee had recommended not be approved. There was concerned expressed that the lung programs within 500 miles of Oregon may not have concurred with this sharing agreement. The Committee noted that it had not see this the additional information that was presented to the Executive Committee and expressed an interest in reviewing the information at its next meeting.

Following the discussion, the following motion was made and unanimously approved by the Committee:

****RESOLVED, that the Executive Committee is directed to meet with the Thoracic Organ Transplantation Committee to discuss the matter of the Region 6 lung sharing agreement that was approved at the November 21, 2003, Board of Directors meeting.**

11. Review of Thoracic Wait-Time Modification Requests – At the January 23, 2004, and the May 14, 2004, meeting, the Thoracic Committee reviewed nine requests for waiting time adjustment under Policy 3.2.1.8. Finding that eight of the requests were supported by the necessary evidence, the Committee voted unanimously to approve those eight thoracic wait-time modification requests. The remaining request that was not approved will be referred back to the requesting transplant center for more evidence. Noting that a majority of the requests reviewed by the Committee listed a clerical error as the reason for requesting waiting adjustment, the Committee agreed to discuss in future meetings methods to prevent errors in thoracic candidate listings.

The case shown in **Exhibit M** requests an adjustment of patient heart waiting time to June 25, 2003, from a current listing date of August 18, 2003. The application includes corroborating documentation from the appropriate heart transplant programs. The application requests a modification of this patient's wait time based on the transplant center's clerical error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit M shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit N** requests an adjustment of patient lung waiting time to June 26, 2003, from a current listing date of August 18, 2003. The application includes supporting documentation and signatures from the appropriate lung transplant programs. The application requests a modification of this patient's wait time based on the transplant center's clerical error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit N shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit O** requests an adjustment of patient lung waiting time to September 18, 2003, from a current listing date of November 16, 2003. The application includes supporting documentation and signatures from the appropriate lung transplant programs. The application requests a modification of this patient's wait time based on the transplant center's clerical error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit O shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit P** requests an adjustment of patient heart Status 1A waiting time to October 3, 2003, from a current listing date of October 10, 2003. The application includes supporting documentation. The application requests a modification of this patient's wait time based on an error in the UNet system that prevented the patient's 1A Status from being extended on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit P shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit Q** requests an adjustment of patient lung waiting time to August 26, 2003, from a current listing date of March 27, 2004. The application includes supporting documentation. The application requests a modification of this patient's wait time based on the transplant center's clerical error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit Q shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit R** requests an adjustment of patient lung waiting time to January 24, 2003, from a current listing date of January 15, 2004. The application includes supporting documentation. The application requests a modification of this patient's wait time based on the transplant center's error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit R shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit S** requests an adjustment of patient lung waiting time to October 20, 2003, from a current listing date of December 23, 2003. The application includes supporting documentation. The application requests a modification of this patient's wait time based on the transplant center's clerical error which prevented the patient from being listed on the requested date. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit S shall be approved for implementation pending programming on the UNOS system.**

The case shown in **Exhibit T** requests a reinstatement of patient lung waiting time between June 20, 2003, and February 4, 2004. During this time, the patient was incorrectly listed as "inactive" due to a clerical error by the transplant center. The application includes supporting documentation and signatures from the appropriate lung transplant programs. The Committee, therefore, offers the following recommendation for consideration by the Board of Directors:

****RESOLVED, that the request for waiting time modification attached as Exhibit T shall be approved for implementation pending programming on the UNOS system.**

12. Responses to OPO Committee Requests – At the January 23, 2004, meeting, the Thoracic Committee considered requests from the OPO Committee to respond to several recommendations and proposals. The Committee unanimously agreed with the OPO Committees recommendation that disposable organ packages should not be reused. Also, the Committee discussed the issue of the role of "coordinating OPO's", and was unable to offer any recommendations at this time.

13. Review of UK Model for Predicting Individual Survival. At the request of the Organ Availability Committee, the Thoracic Committee reviewed the article "Predicting Patient Survival in the Kidney Transplant Assessment Clinic: A Practical Clinical Assessment." The Committee applauded the authors on their research, and noted that a system of allocation based on urgency and benefit is currently being proposed by the Thoracic Committee for lung allocation.

OPTN/UNOS THORACIC ORGAN TRANSPLANTATION COMMITTEE MEETING

January 23, 2004
Chicago, Illinois

Committee Members in Attendance

O. Howard Frazier, M.D.	Chairman
Edward R. Garrity, Jr., M.D.	Vice-Chairman
Jonathan A. Hammond, Jr., M.D.	Region 1
Mark J. Zucker, M.D.	Region 2
J. David Vega, M.D.	Region 3
Abbas Ardehali, M.D.	Region 5
Gary Y. Ott, M.D.	Region 6
Jeffrey D. Hosenpud, M.D.	Region 7
Wayne E. Richenbacher, M.D.	Region 8
Charles C. Canver, M.D.	Region 9
Alvise F. Bernabei, M.D.	Region 10
Martin R. Zamora, M.D.	At-Large
Frederick Grover, M.D. (by phone)	At-Large
Wayne D. Babcock, RN,CPTC	At-Large
Richard C. Daly, M.D.	At-Large
Thomas M. Egan, M.D.	At-Large
Elbert P. Trulock, III, M.D.	At-Large
Barbara Elick, R.N., CCTC	At-Large
W. Steves Ring, M.D.	At-Large
Seth Kramer, J.D.	At- Large

Committee Members Unable to Attend

R. Douglas Ensley, M.D.	Region 4
Mark K. Robbins, M.D.	Region 11
Joseph Petro	At-Large
Kimberly Davis, RN, CPTC	At-Large

UNOS/HRSA/URREA Staff in Attendance

Douglas A. Heiney, BBA, Director, UNOS Department of Membership and Policy Development
Leah Bennett Edwards, Ph.D., Assistant Director, UNOS Department of Research
Matthew A. Coke, J.D., Policy Analyst, UNOS Department of Membership and Policy Development
Katrina Goodwin, M.M., UNOS Department of IT Development
Donna Rilee, UNOS Department of IT Development
Michael Dreis, PharmD, Government Liaison, HRSA, Division of Transplantation
Jin Kim, Government Liaison, HRSA, Division of Transplantation
Robert Merion, M.D., SRTR
Susan Murray, Sc.D., SRTR
Rami Bustami, PhD., SRTR
Tempie Hulbert-Shearon, PhD.,SRTR

OPTN/UNOS THORACIC ORGAN TRANSPLANTATION COMMITTEE MEETING

May 14, 2004
Chicago, Illinois

Committee Members in Attendance

O. Howard Frazier, M.D. (by telephone)	Chairman
Edward R. Garrity, Jr., M.D.	Vice-Chairman
Jonathan A. Hammond, Jr., M.D.	Region 1
Mark J. Zucker, M.D.	Region 2
J. David Vega, M.D.	Region 3
R. Douglas Ensley, M.D.	Region 4
Abbas Ardehali, M.D.	Region 5
Gary Y. Ott, M.D.	Region 6
Jeffrey D. Hosenpud, M.D.	Region 7
Wayne E. Richenbacher, M.D.	Region 8
Charles C. Canver, M.D.	Region 9
Alvise F. Bernabei, M.D.	Region 10
Thomas M. Egan, M.D.	At-Large
W. Steves Ring, M.D.	At-Large
Stuart Sweet, M.D.	At-Large
Martin R. Zamora, M.D.	At-Large
Wayne D. Babcock, RN,CPTC	At-Large
Kimberly Davis, RN, CPTC	At-Large
Richard C. Daly, M.D.	At-Large
Barbara Elick, R.N., CCTC	At-Large

Committee Members Unable to Attend

Mark K. Robbins, M.D.	Region 11
Frederick Grover, M.D. (by phone)	At-Large
Elbert P. Trulock, III, M.D.	At-Large
Seth Kramer, J.D.	At- Large
Joseph Petro	At-Large

Guests
Russell Weisner, MD, President, UNOS Board of Directors
Dr. Larry Hunsicker, MD, Chair UNOS/SRTR Data Working Group

UNOS/HRSA/URREA Staff in Attendance

Russell Weisner, MD, President, UNOS Board of Directors
Douglas A. Heiney, BBA, Director, UNOS Department of Membership and Policy Development
Leah Bennett Edwards, Ph.D., Assistant Director, UNOS Department of Research
Matthew A. Coke, J.D., Policy Analyst, UNOS Department of Membership and Policy Development
Donna Rilee, UNOS Department of IT Development
Henry Krakauer, M.D. (by phone), Government Liaison, HRSA, Division of Transplantation
Hui Hsing Wong, M.D., J.D., Government Liaison, HRSA, Division of Transplantation
Monica Lin, Government Liaison, HRSA, Division of Transplantation
Robert Merion, M.D., SRTR
Robert Wolfe, PhD., SRTR
Rami Bustami, PhD., SRTR
Tempie Hulbert-Shearon, PhD.,SRTR

BRIEFING PAPER **UNITED NETWORK FOR ORGAN SHARING**

Allocation of Lungs:

Proposed Amended UNOS Policy 3.7.6 (Status of Patients Awaiting Lung Transplantation), Policy 3.7.9.1 (Waiting Time Accrual for Lung Candidates with Ideopathic 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**.

EXHIBIT A

- **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 all types of transplant candidates 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.

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[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

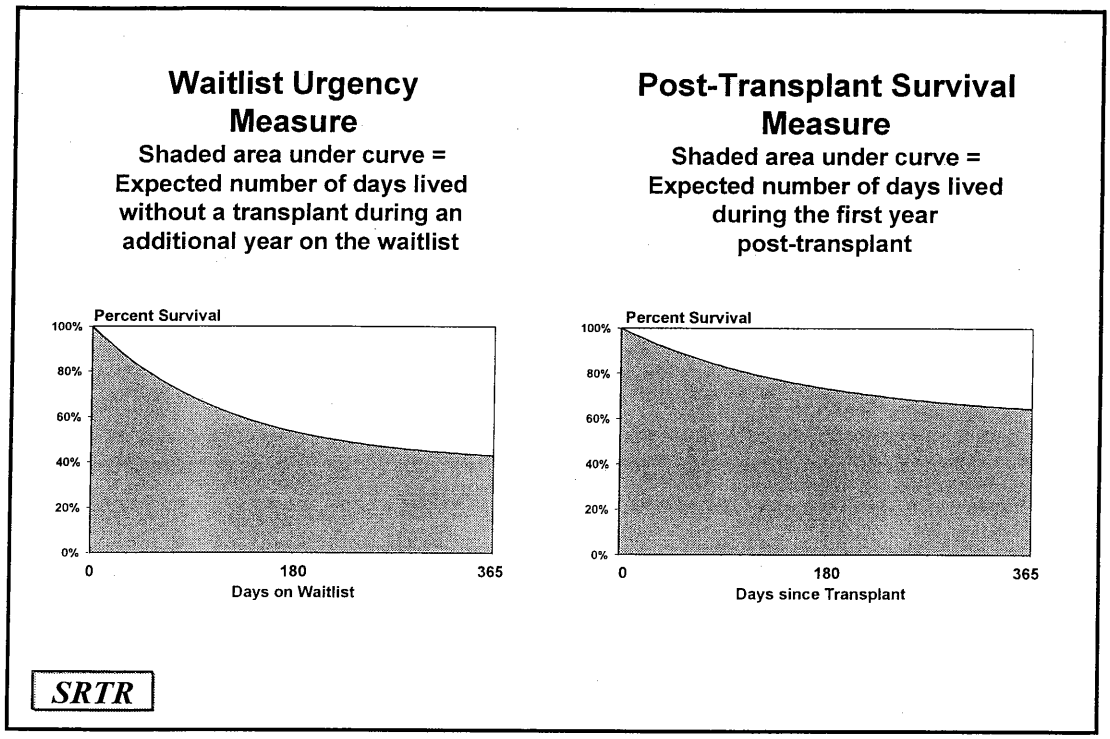
E. *Mechanics of the Proposed Lung Allocation Algorithm*

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



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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.

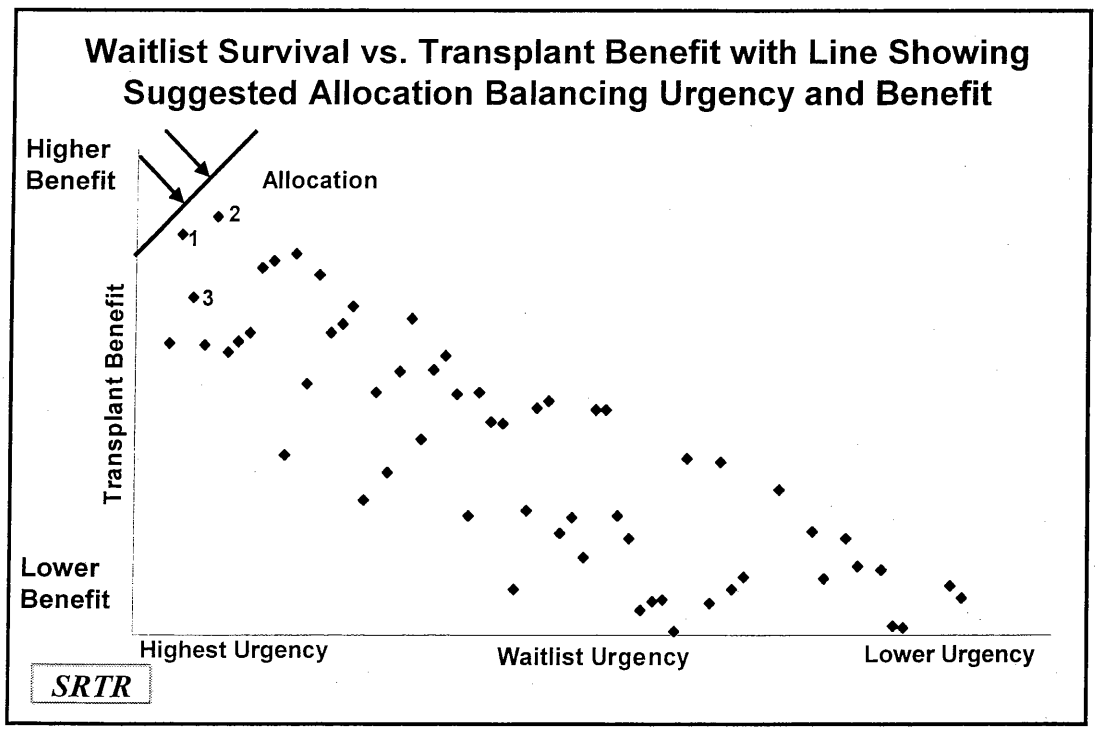
[5] In response to public comment to the prior proposal, the Committee considered whether to use 1-year or 2-year post-transplant survival measure in the algorithm. Allocation scores resulting from these two alternative calculations were in very close agreement (correlation greater than 0.999). The Committee 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

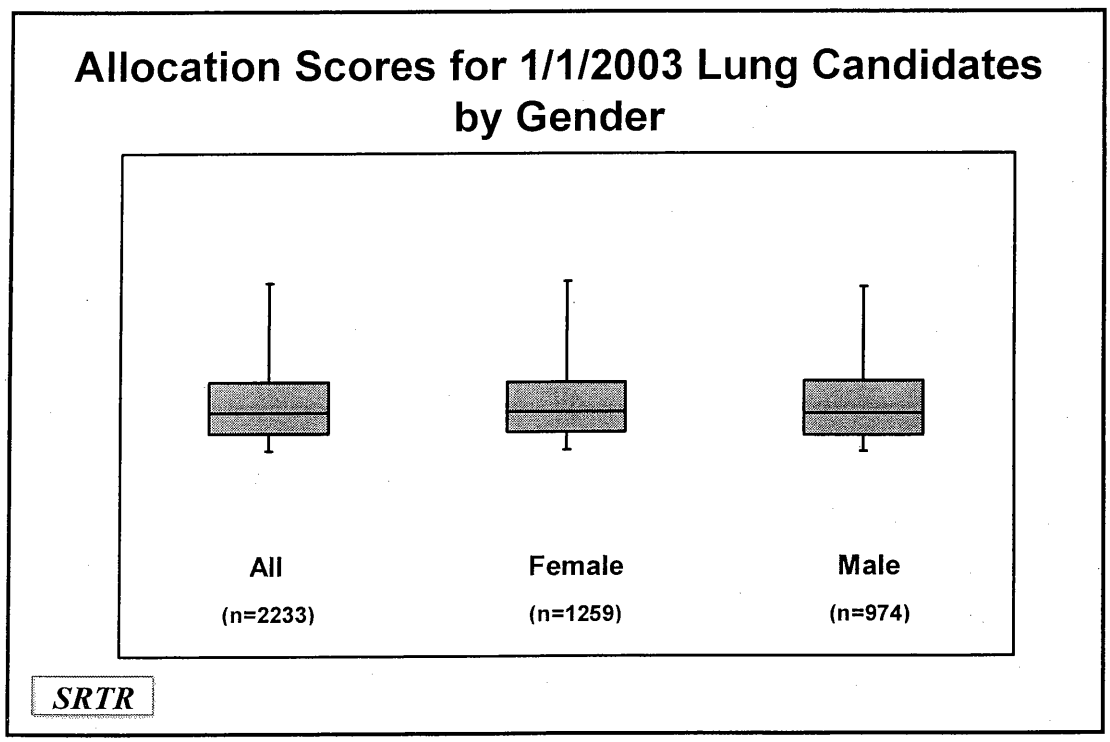


Figure F-2

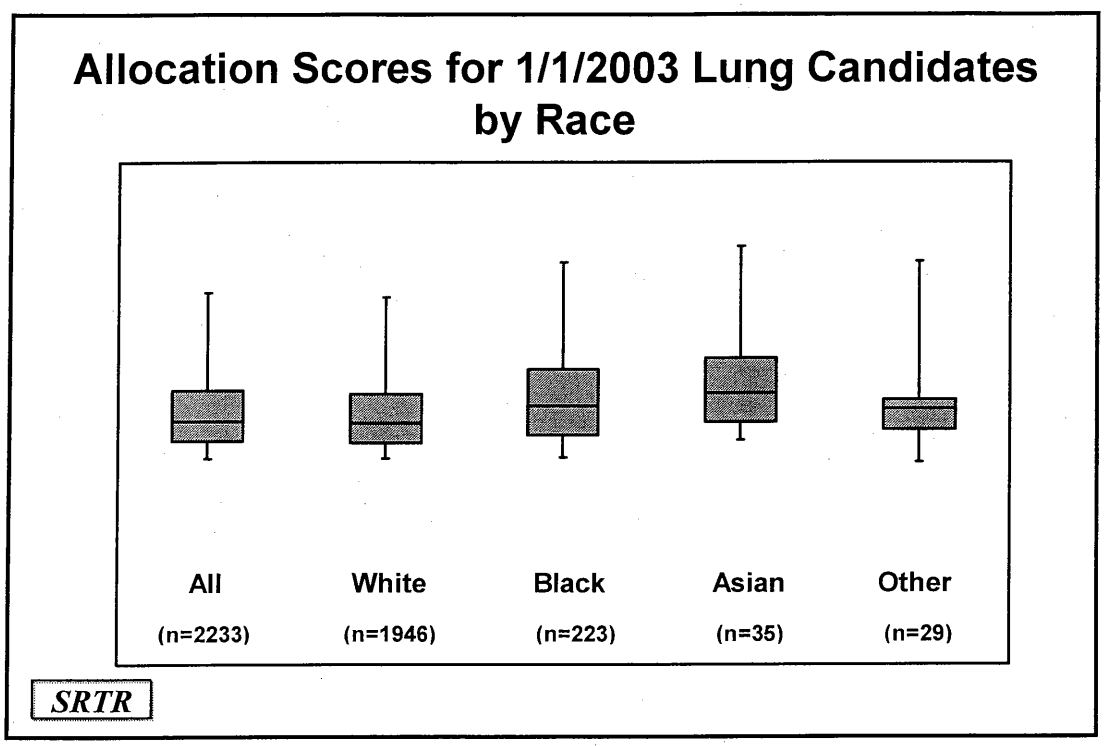


Figure F-3

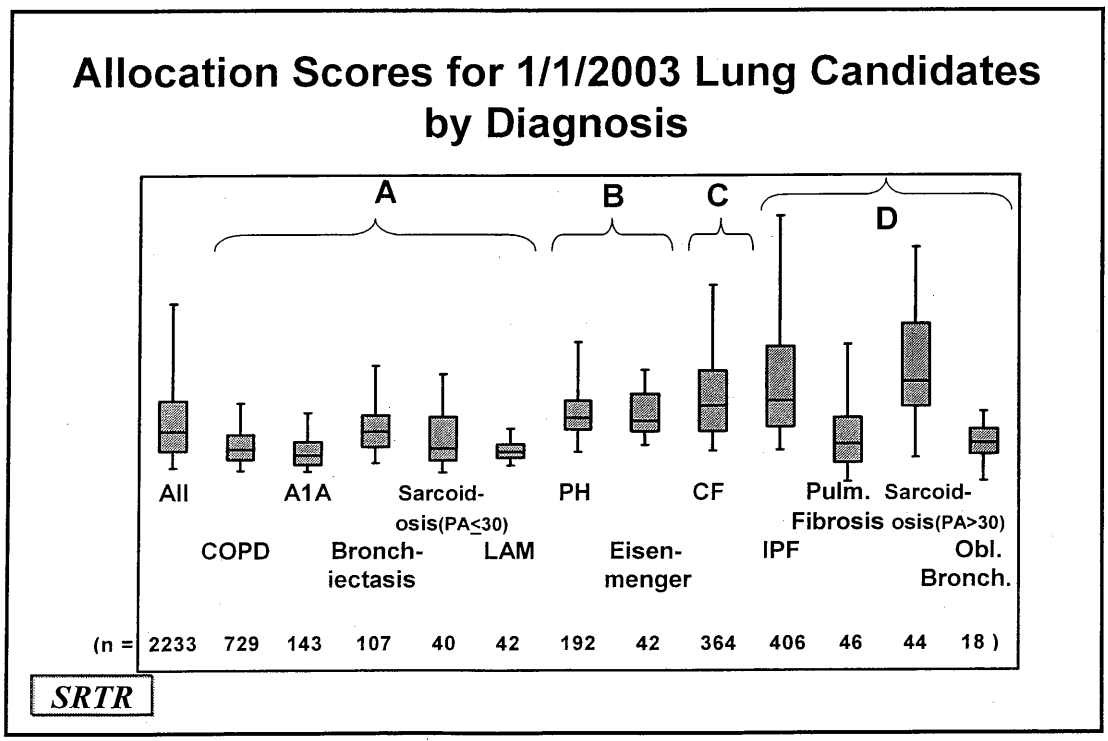
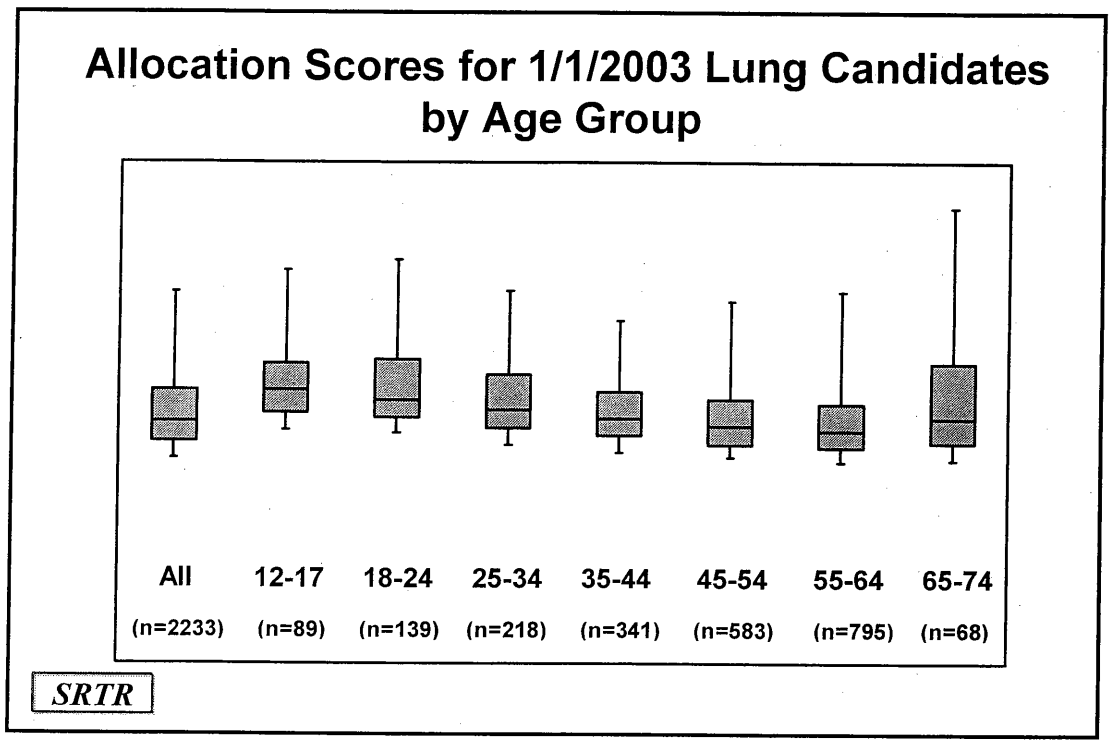


Figure F-4



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.

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

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** Lung Allocation.**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

Table 2

[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).

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)

7. Lung Subcommittee Action and Path Forward

At the May 14, 2004 meeting, the Lung Subcommittee met to respond to public comment. 199 responses were submitted to UNOS regarding this policy proposal. Of these, 147 (73.87%) supported the proposal, 42 (21.11%) opposed the proposal, and 10 (5.03%) had no opinion. Of the 189 who responded with an opinion, 147 (77.78%) supported the proposal and 42 (22.22%) opposed the proposal. The proposal was reviewed by the Regions and received overall support in 9 of 11 Regions.

In response to public comment and from its own deliberations, the Lung Subcommittee and the Thoracic Committee made several revisions to the policy proposal that was submitted for public comment and agreed to incorporate those revisions into the final proposal to be submitted to the Board of Directors for approval. The final proposal will include the following changes:

- A **Lung Regional Review Board** will be created as a way to give patients and clinicians an avenue to pursue when they believe that a patient may fall outside the goals of the system. The Subcommittee agreed to create the review mechanism with general policy language in the proposal, but to organize the RRB and set case review time limits and guidelines in future meetings prior to implementation of the system. The specific policy provisions for the Lung RRB will be submitted for approval by the Board of Directors.

- Transplant centers will be required to update their candidates' clinical diagnostic values on the UNet system at least one time every six months.

- Because of risks associated with the procedure, collection of clinical diagnostic variables that are obtainable only by right heart catheterization will be left to the discretion of the transplant center.

In addition, the Subcommittee agreed to produce easy-to-understand materials to explain the new lung allocation system to patients and transplant professionals. The Subcommittee also recommended holding a national forum within the first two years following implementation to gather feedback from the transplant community on the new system.

The Thoracic Committee intends to submit the proposed changes to lung allocation policy to the Board of Directors at the June 24-25, 2004 meeting. If approved, UNOS will undertake programming and implementing the lung allocation system. It is expected that data from the Retrospective Lung Data Collection project will be fully analyzed by the November 2004 Board of Directors meeting. It is also expected that the first revisions to the lung allocation system based on the retrospective data analysis will be presented by the Thoracic Committee at that meeting.

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.

Summary of Public Comments

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)

As of 5/9/2004, 199 responses have been submitted to UNOS regarding this policy proposal. Of these, 147 (73.87%) supported the proposal, 42 (21.11%) opposed the proposal, and 10 (5.03%) had no opinion. Of the 189 who responded with an opinion, 147 (77.78%) supported the proposal and 42 (22.22%) opposed the proposal. Comments on the proposal received to date are as follows:

I: Individuals Comments:

Comment 1:
vote: Oppose

I am a patient with cystic fibrosis and have I accrued over a year and a half on the lung transplant list. I am currently close to being activated for transplant. My lung transplant center would have activated me in March if I did not express the deep desire to graduate from school in May. When I am activated I will move over 800 miles from my home to the city of my transplant center. My parents will also leave their home, take leaves of absences from their jobs, to live with me and be my caregivers. We will therefore need to rent an apartment while we wait for the call. However, after reading the proposed amendment to the allocation of lungs, and discussing them with my doctor, I am certain that I would not qualify for "top" priority. My condition is very serious, and I have been struggling for a long time. All my doctors believe that we are quickly running out of options with my current lungs, and all strongly recommend I have a lung transplant soon. I attempt to remain very active, I do not use oxygen (a proposal factor), partly because I make sure take excellent care of myself and I know regular exercise will make my transplant more successful. Moreover, I know that I would likely not be "high" priority, because there are patients waiting with lower PFT's. Thus, if these proposals do pass, I ask you to consider patients such as me when you are choosing a date to make them effective. I will be in an unknown city, in a rented apartment, waiting for much needed lungs. At one point I will have been told that I am the next person to be called for my lung specifications. But then, if these proposals become effective during this time, I will likely be told that I am suddenly not next and will have to wait longer. Thus, I will cause my parents more expense due to their leaves from work and they will incur additional expenses because we will need to live away from home longer. This situation would cause my family an even bigger financial burden. In addition, we would feel great emotional anxiety because the "rules" will feel like they "keep changing" thus possibly shaking our confidence with the entire transplant process. Currently, I feel very confident because I know transplant centers are experienced and have established rules and guidelines that enable them give me a very successful transplant procedure. Please, when considering these proposals and a possible date to make them effective, please consider people in this situation. We are all very sick and we all need lungs very badly. Please if choosing an effective date, allow enough time for patients to get acclimated to the new proposals, so the changes won't cause additional anxiety, panic and expense during a very frightening time.

Committee Response:

There will be a sufficient period of time until implementation of the lung allocation algorithm that will be sufficient for transplant centers to adjust to the new system, screen their patients, and enter their patient's clinical diagnostic values into the system.

Comment 2:
vote: Oppose

1. The change to the new system for thoracic organ allocation is an unfunded mandate. In order to comply with the new system centers will need to hire additional administrative and clinical personnel. There is no method for financial support of these new requirements. 2. The clinical testing required under the new system to obtain listing for lung or heart-lung transplantation, and for subsequent periodic updates of status, will represent a significant barrier to obtaining a transplant for many patients. At best such additional testing will prove inconvenient to patients, and at worse, it may prove dangerous. For example, requiring right heart catheterization to obtain hemodynamic data in critically ill cystic fibrosis patients is only justified if such information has proven prognostic and diagnostic utility. In this instance there is no data supporting such a practice. 3. The UNOS database alone does not provide for an accurate prognosis in patients awaiting lung and heart-lung transplantation. Prognostic models of proven utility already exist and include variables, which are not included in the proposal. For example, the Liou prognostic model for survival in cystic fibrosis, and the CF Foundation Registry are well validated and contain important variables for prediction of outcome in CF patients which are not included in the UNOS database. Similarly an NIH trial of survival in patients with pulmonary arterial hypertension generated an important prognostic equation for patients with PAH and important variables from this study are not included in the current proposal. 4. The new system may encourage clinical practices that are not in the best interest of patients with end-stage pulmonary disease. a. Employing ventilator use as a factor to predict the risk of death on the list may but may provide for worse overall clinical outcomes. It is unclear that patients who are invasively ventilated should hold onto their "priority" for risk of death, thus higher priority for transplant, beyond a set time period. That is, patients on ventilators are known to accumulate complications, including nosocomial infections, at an accelerating rate based on days on the ventilator. Thus under the new system if these patients are given higher priority and thus receive transplants the principal of optimizing benefit will be violated as they may suffer much worse outcomes following transplantation. The new policy may encourage centers to place patients on ventilators in the hopes of improving their place on the waiting list. Such decisions may be in conflict with the best interests of the patients and could be to the detriment of their medical care, which, in critically ill patients, includes appropriate discussions of end-of–life care, the reasonableness of certain interventions, an understanding of the concept of futility and the role of any advanced therapy in a patient with little chance of meaningful survival. b. The use of insulin dependent diabetes as a factor used to predict risk of death on the list may advantage some of the worst candidates for transplantation. The inclusion of this criteria may be meant to benefit cystic fibrosis patients with CF-related diabetes but its unintended effect may be to prioritize for transplant a group of patients who in general are at higher risk for operative and post-operative transplant complications, and thus poorer outcomes. 5. The new scoring system is too complex and will generate confusion among patients and their providers. The concept of "waiting time' on the list under the current system is easily understandable to patients and their families, and despite its limitations the current system offers less opportunity for misuse and misunderstanding.

Committee Response:

The Subcommittee acknowledges that in some instances there may be increased costs associated with complying with the data-entry components of the proposed lung allocation system. However, the Committee feels that these cost increases will be minimal over time. Periodic updates of clinical variables on the system are essential to providing current information on candidates' medical conditions and are essential to maintaining the accuracy and fairness of the system. The Subcommittee acknowledges the risks to specific patients during a right-heart catheterization, and has agreed to leave the frequency of this testing to the discretion of the treating physicians. The Subcommittee acknowledges that a variety of test data exist on patient groups, however,

the UNOS database was used as a central repository of data specific to lung transplantation and common to all patients on the UNOS lung waitlist. The Subcommittee has recently completed a data collection project to recover retrospective serial data on a large sample of individual patients at centers around the country. The data analysis from this project will be used to update the lung allocation algorithm with additional factors that may prove to be predictive of transplant urgency and benefit in patients. The Subcommittee considered ventilator use as a factor in predicting urgency and benefit, and acknowledges the pre-transplant and post-transplant risks assocociated with ventilator use. It is likely that the lung allocation will offset these two risk factors before and after the transplant. The data evaluated by the Subcommittee suggested that insulin-dependent diabetes is a factor predictive of survival and should be used in the proposed algorithm. The Subcommittee understands the complexity of the proposed system, and following implementation of the system, the Subcommittee will begin work on explanatory materials for patients and their families.

Comment 3:
vote: Oppose

Allows for arbitrary opinions considering "most benefit" which could lead to abuse of the organ distribution system by wealthy or influential individuals waiting for organs.

Committee Response:

Wealth and social position are not factors in allocation of lungs or any other organ.

Comment 4:
vote: Oppose

Alpha-1 Association Newsletter -April 2004 "Lung Transplants - HHS's OPTN/UNOS Annual Report for 2003" by Bettina Irvine Lung and liver transplants are the end stage treatment for Alpha-1 patients. Over 1,600 of Alphas were transplanted over the last decade, about the same as cystic fibrosis. About half were lungs and half were liver. This Annual Report focuses on the controversy over the allocation of lungs. The present allocation system, which has worked well for so many, is "time on the list", as well as blood type and size. Patients are listed only when they meet established medical criteria. The standard is an FEV1 of less than 25%, when many of us are on oxygen and struggling. Certain other lung diseases may get special consideration: an extra 90 days of accrued wait time for IPF, or more liberal criteria encouraging a timely evaluation and listing. The OPTN/UNOS Subcommittee for Lung Allocation seems to suggest that patients with obstructive lung disease are "gaming" the system by being listed too early and that there are no survival benefits for the large number of patients with COPD. The subcommittee has recommended replacing "time of the list" with a new system based upon disease category prioritizing the "sickest" groupings and without grandfathering patients currently waitlisted. Alphas have joined other patient groups in raising serious objections to the proposed change. Lumping Alpha-1 into a larger disease category including COPD, LAM and Sarcoidosis negates Alpha-1's unique genetic origins as well as the positive post TX long term survival statistics. If enacted, says Dr. Sandy Sandhaus, Clinical Director of the Alpha-1 Foundation, the changes "raise the specter that Alpha-1 patients may never receive transplants." Miriam O'Day, the head of A1A's new Public Policy Office, submitted a joint letter from the Alpha-1 Association and the Alpha-1 Foundation expressing our concerns. We were joined in our opposition by the Pulmonary Hypertension Association, COPD-ALERT, EFFORTS,

the Bioethics Center of University of Minnesota, and the American College of Chest Physicians and the OPTN/UNOS Pediatric Transplantation Committee. As a direct result of Miriam O'Day's successful advocacy efforts, the head of HHS's Division of Transplants wrote her saying the proposed change in the allocation system had been delayed until our concerns were addressed. According to the published minutes of OPTN/UNOS board meeting in November, there was overwhelming opposition to the subcommittee's proposal. Of the 163 who responded with opinions, 71% opposed the proposal and 29% supported it: over 2-to-1 against. Of the 11 UNOS Regions, 5 opposed it, 5 supported it and one supported it but only with amendments. Moreover, it was noted in the minutes that two of the Regions which supported the measure met in a combined session, and "only two physicians/surgeons currently involved in thoracic organ transplantation were present for the discussion". After reviewing these comments, the consensus is that for appropriate disease grouping, more up-to-date serial data collection on each disease is needed and long-term survival should be a key factor in forming the algorithms. Moreover, before implementing any new allocation system, there should be an analysis done prospectively for a one year period and then presented again to UNOS, based upon stronger data in order not to be stuck with a new system which is just as subjective as the one presently in place. Any proposal also must be written in a manner easily understood by the layman. A new updated proposal is being prepared for public comment this spring, which may be considered at the June board meeting of OPTN/UNOS. Alpha-1 organizations are in the process of organizing a one day roundtable discussion representing patient advocates who have responded to the proposed system. The roundtable aims to capture the end-user patient perspective and organize this into public comments for UNOS. It is important that a fair and equitable access be given to this scarce resource, the ultimate gift of life. The debate is ongoing. Dr. Arthur Caplan, Director of Center for Bioethics at the University of Pennsylvania Medical School endorses the call for a public meeting. He believes the public which donates lungs does so in the belief that it is saving lives regardless for the reason for lung failure. Dr. Caplan says it is absolutely crucial that all segments of those involved in lung transplantation- medical groups, donors, donor families and potential recipients and their families - fully understand and support the rules and algorithms used to allocate these scarce life-saving resources. He calls upon HHS to create a forum in which the allocation of lungs for transplant and for research can be openly and fully discussed.

Committee Response:

The Subcommittee acknowledges that the current-time waiting system has been effective for those patients who have received a transplant under the system. However, the Subcommittee believes that a system based on urgency and benefit and actual clinical diagnostic data, not waiting time, would have greater benefits and successful results for a far greater number of transplant candidates than the current system. The genetic origin of Alpha-1 is not a factor in allocation, rather, objective clinical diagnostic data are factors for all allocation of lungs to patients with all lung diseases regardless of origin. Transplant candidates with Alpha-1 will be transplanted according to their objective diagnostic medical criteria. The Subcommittee understands the complexity of the proposed system, and following implementation of the system, the Subcommittee will begin work on explanatory materials for patients and their families. A national forum for transplant professionals was held in March 2003 at which surgeons and physicians from across the country gathered to offer their input and reviews of the proposal. Since that meeting, the proposal has been extensively revised to reflect the opinions of the transplant community at that meeting.

Comment 5:
vote: Oppose

As an Alpha1 patient who is not eligible for transplant, I do not want to see others loose the chance at extending their lives. Why would anyone feel it is better to wait until a patient is critical? Sorry, but that makes no sense.

Committee Response:

The proposed lung allocation does not wait until a patient is critical. Rather it seeks to determine the time to transplant that will provide the optimal benefit for patients post-transplant.

Comment 6:
vote: Oppose

As quoted from above: "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." If this were the case my husband would have passed the first criteria, BUT not the second as he was 64 years old. Who is to decide how long a person has left to live (expected to receive the greatest survival benefit)....How would his case have been decided and who would have been appointed to play GOD. He was desperately in need of a lung, but since he was 64 and going to die eventually, does that mean he would have been passed over for someone younger??? I'm opposed to this proposal. I feel everyone, young and old should have equal opportunity for a transplant. My husband is now all most a year out and doing very well. He is also 67 years old and still going strong...

Committee Response:

Age is a factor in determining survival along with many other factors. As such, age must be considered, collectively, with other factors in allocation. However, age alone does not exclude anyone from the opportunity for a transplant under the proposed system.

Comment 7:
vote: Oppose

Comment regarding Lung Allocation Proposals: I have concerns regarding the validity of generating such detailed prognostic models based on retrospective analysis of limited UNOS data My level of concern differs with respect to diagnostic category and the use of waitlist urgency score vs. the post-transplant survival measure. Thus, I will outline my thoughts below: 1) We do need a waitlist urgency prioritization system. However, I would propose that we are not yet ready to proceed based on the inadequate criteria in this proposal for transplanting PH patients. a. For the majority of the pulmonary diagnoses, the benefit of using the proposed model seems to outweigh the concerns regarding accuracy, and the stated intention/process of additional data retrieval/collection with ongoing discussion/refinement of models sufficiently addresses these concerns for most of these groups. We will not be able to progress in the direction of incorporating a waitlist urgency measure within a reasonable timeframe if we await perfect data. b. However, the pulmonary hypertension subgroup presents unique challenges in terms of establishing LT criteria, and the proposed criteria are likely to be truly inadequate based on their reliance on functional class rather than incorporating criteria based on right heart catheterization and echocardiography. . 2) The proposed post-transplant survival measure is problematic for three reasons and based on these concerns should be eliminated from the proposal. a. It is unclear that national data adequately reflect

post-transplant success at individual institutions. Those institutions such as The Cleveland Clinic who transplant high-risk patients perform a service for patients who present with a critical level of urgency as well as for the lung transplant community in improving our expertise in transplanting more difficult patients. If these patients are de-prioritized based on nationwide data, it may represent a setback in the field and a disservice to critically ill patients, many of whom are young. The individual transplant centers have sufficient motivation to maintain their survival statistics and sufficient safeguards in place in the form of selection committee criteria with respect to the patients they list, so that they are unlikely to list patients who will not survive. Removing the discretionary role of the institution for these patients is a serious concern. b. Again, this issue is particularly urgent with respect to pulmonary hypertension patients who are de-prioitized in this proposal based on national data generated from all centers, many of which do not have expertise in management of pulmonary hypertension. The pulmonary hypertension patients are precisely those who need the highest prioritization if they are to be transplanted. We should not be listing these patients early before they fail therapy, but once they do fail therapy, they are likely to die if they are not promptly transplanted. We are making rapid progress in the care of pulmonary hypertension patients, and the opportunity to establish the role of lung transplantation in their care is important for this field and these patients. Assigning these typically young, highly urgent patients the same score as a 65 year old with stable COPD may preclude transplant as a therapeutic option for this group. c. The statement is made in the proposal that the purpose of the post-transplant survival measure is to prevent allocation to those patients who are "unlikely to survive and whose lives could not be prolonged by transplantation". This seems to be a misrepresentation of the post-survival score. In fact, most of the patients who are higher risk are likely to survive although at some centers they may be less likely to survive than a less ill patient. In addition, it is not accurate to say that their lives "could not be prolonged" when the issue is again the likelihood of success relative to other diagnoses. It is not clear that the difference in survival for groups/individuals in most cases is of such a magnitude that it reaches a level of ethical relevance that ought to determine allocation priority. The ethical relevance of the survival differences should be defended based on ethical criteria rather than making a statistical argument alone. For these reasons, I would propose: 1) Eliminating the post-transplant survival measure 2) Developing a prioritization system based on waitlist urgency alone 3) Convening a group of experts in pulmonary hypertension to develop waitlist urgency criteria for this group using data other than UNOS data. Sincerely, Constance A. Jennings, MD Director, Pulmonary Vascular Program Department of Pulmonary and Critical Care Medicine Transplantation Center The Cleveland Clinic Foundation Cleveland, Ohio

Committee Response:

The Subcommittee agrees that, by collecting serial data, by using the retrospective data that has been collected already, and allowing candidates to update their data as frequently as necessary, it will be able to identify PH patients who will benefit from transplant. Unfortunately, PH patients may experience sudden declines in their conditions, and these events are very difficult to predict. It is hoped that by allowing candidates to update their data in the system as frequently as necessary to reflect severity, those PH patients who experience sudden declines can be allocated lung before they are too sick to transplant.

The Subcommittee considered eliminating post-transplant survival as a component of the system, but determined that by eliminating this element and allocating lungs based on waitlist urgency alone, the system would be allocating lungs to patients who may be too ill to survive.

The Subcommittee expects that the analysis of the retrospective data collected, and the future collection of serial data, will yield additional factors that evaluate waitlist urgency among PH patients.

Comment 8:
vote: Oppose

Cumbersome, confusing, time consuming.

Committee Response:

The Subcommittee understands the complexity of the proposed system, and following implementation of the system, the Subcommittee will begin work on explanatory materials for patients and their families.

Comment 9:
vote: Oppose

I am and have been on the lung transplant wait list for 1.5 years. I have un-rooted my family and temporarily relocated to San Diego from Phoenix because I am high on the list and was told to do so. Now your proposing a change in priority. Those of us that have been listed must be grand fathered in or allowed to remain at their current position. Changing them (us) would be totally unfair and demorializing.

Committee Response:

There will be a sufficient period of time until implementation of the lung allocation algorithm that will be sufficient for transplant centers to adjust to the new system, screen their patients, and enter their patient's clinical diagnostic values into the system.

Comment 10:
vote: Oppose

I believe that the allocation determined solely on wait time is the fairest way.

Committee Response:

The Subcommittee thanks you for your opinion.

Comment 11:
vote: Oppose

i feel patients will be to sick and surival rate will go down.

Committee Response:

The proposed lung allocation does not wait until a patient is critical. Rather it seeks to determine the time to transplant that will provide the optimal benefit for patients post-transplant.

Comment 12:
vote: Oppose

I feel that some centers will say candidates are sicker then so they move up fastser.

Committee Response:

The proposed system requires that candidates' data is updated at regular intervals. It is anticipated that frequent updates will accurately reflect the severity of illness and preserve the accuracy of the system.

Comment 13:
vote: Oppose

I have a question. What about the patients that have AB type blood. There are only about 2% of all transplants nationwide that are AB blood types.....I think that is just as serious as being very ill. We may not get the organs at all with our waiting time on the lists.

Committee Response:

ABO identical and compatible matches will continue to be a factor in allocation just as they are in the current system.

Comment 14:
vote: Oppose

I have Alpha 1 and don't think it would be fair to me. I was listed in 1998 nd went inactive in 2000 because my center told me I had gotten myself in to good of shape with exercising so put be on inactive in June 2000. I feel that with having Alpha 1 and being linked to all COPD that I won't get a fair chance unless I get really sick and I'm not the type that will let myself get to bad because records show that the people who exercise and keeps theirselves as healthy as they can would be treated unfairly.

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Waitlist urgency and post-transplant benefit are the factors measured by the algorithm, not waitlist time.

Comment 15:
vote: Oppose

I have been on the list a long time without a transplant. I allowed those needing it more to move ahead of me, but now I am really sick and may not get my transplant on time. This new law may make it harder for me to get my new lungs on time hence, I may not make it. They shouldn't change the rules when everyone was told ahead of time what the deal was.

Committee Response:

There will be a sufficient period of time until implementation of the lung allocation algorithm that will be sufficient for transplant centers to adjust to the new system, screen their patients, and enter their patient's clinical diagnostic values into the system.

Comment 16:
vote: Oppose

I have had a single lung transaplant, 14 months ago. I feel the current method is the best and most fair.

Committee Response:

The Subcommittee wishes you continued success with your transplant and thanks you for your opinion.

Comment 17:
vote: Oppose

I have IPF and have been waiting on the list for two years. I take good care of myself and seek regular medical attention. I would not want someone who does not follow this pattern to be moved around me because they failed to follow basic health regulations or because they didn't seek medical attention sooner. If they can bump me off my spot on the list and get an organ ahead of me, who is to say that I will make it to the next available matching donor? Everyone should have to bide their time on the list and take their chances in doing so. If a patient is doing well enough that they can CHOOSE to let someone get an available organ before them despite waiting longer, that is a choice that the doctors and the person with more "seniority" on the list should make. It should NOT be made for them.

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Waitlist urgency and post-transplant benefit are the factors measured by the algorithm, not waitlist time.

Comment 18:
vote: Oppose

I have Primary Pulmonary Hypertension, and I am currently awaiting a double lung transplant at UCLA. I have been listed for almost one year (May 5, 2003), and the available medications for my disease are not affective. I am only 51, and have always been in good health. Until PPH, I was a very active person. I am fearful that the old statistics being used regarding PPH patients may take away my chance at transplant. I read many posts on a message board regarding CF patients and their many bouts with infection post-transplant. I hope to be "cured" of PPH after transplant, and I look forward to another 20+ years of living. I urge you to review newer statistics, and take into account the many variables of each individual recipient.

Committee Response:

In preparing the current proposal, the Subcommittee used survival data for cohort of PPH patients listed for transplant between 1999 and 2001. Once the proposal is implemented, the Subcommittee intends to continue to update the algorithm with current survival data for each diagnosis group.

Comment 19:
vote: Oppose

I have read the proposed changes 4 times and still am not 100 percent sure of what you are proposing. It would seem that the sickest patient, who you would put at the top of the list, might be too sick to have a good chance at survival. How exactly would you determine who has the best chance of survival - seems like a pretty subjective task. Lastly, if everyone would have a point score, why would they be divided into groups? Would the score not be the score? I definitely think this proposal needs a lot of further consideration and discussion before any changes are enacted.

Committee Response:

In the course of analyzing risk factors, the Subcommittee found it useful to evaluate those risk factors based on pathophysiology. It became clear to the Subcommittee that different types of lung disease exhibit different patterns and effects. The Subcommittee then felt it legitimate to classify diseases based their similarities to each other. The disease groups are not used to pigeonhole patients or to favor any one group over another.

Comment 20:
vote: Oppose

I have several concerns, and I will break them down by section of the proposed amendment. General Summary: The current proposal seems judgmental, as it implies those of older age have decreased benefit-this is an assessment of worth over medical need. Transplant should not be subjective, but rather objective. There are instances where an older candidate may have improved chances of survival, i.e. end stage CF with vent dependency, etc. B-Features of Current Proposal - It is difficult to appreciate the method by which "post transplant survival measure" is determined - are

we giving all candidates a 77% chance of living through the first year (thus taking &&5 of 365 days?) or is there a formula we are using to determine this "survival number?" J - Updating Candidate Variables: Currently we are using the following measures as determinants for patients nearing their "transplant window of opportunity": 6 minute walk, CPET, Room Air ABG's, and pulmonary function testing. The cumulative results are recorded in a serial fashion, thus allowing any trends to become obvious to the reviewer. In turn, those patients with a more rapid process of functional decline are considered more urgently in need of transplantation than those who are otherwise stable. I believe these markers should be utilized for any lung allocation system that we develop, as they are among the better indicators of a patient's overall functional status. L-Implementation of proposed lung allocation algorithm...: Assigning candidates a value of zero because they have "incomplete" testing data is quite simply unfair. These patients can be retested, but as well all know, both providers and medical centers are under the restriction(s) of the insurance companies. Many companies will only authorize high cost diagnostics annually, or even less. The insurance company may warrant a cardiac catheterization as unnecessary, and the hospital is not able to test their patient. Furthermore, most patients undergo annual routine updating of all diagnostic studies, but these dates may not fall into the time frame of implementation. I propose that this new system, if at all implemented, is done so on a trial basis for a period of at least one full year thus allowing for all currently listed patients AND all newly listed patients to have data entered that is complete and will therefore yield a more reasonable allocation score than that of "zero." 5-Additional proposals to support... Section a-Data Collection - who were the centers that this data was collected from, i.e. were all lung transplant centers included? Can there be a period of time allocated for all lung centers to submit their data, (whether by survey or online data entry), to ensure that this algorithm is adequate and truly fair? Attachment A - Disease specific data elements: regarding CF patients - is there any plan to include a sub group for CF patients colonized with Burkholderia cepacia species? Is risk stratified as greater for these patients? (Possibly it should be, as those with this organism tend to have less than desirable outcome post transplantation.) Or for those patients colonized with any burkholderia species? And in the event that we consider this colonization to be indicative of greater risk, how do we factor it into to algorithm since most CF patients are of a younger age group? Conclusion: I wholeheartedly agree that the Lung Allocation system needs to be redeveloped into a model that reflects both disease acuity and survival benefit. And though there is no clear way to identify these patients by status (similar to the cardiac system), I feel that would be a more ideal method to begin developing a lung allocation system...one where the patients most critically ill are given an better chance at possible transplantation and thus improved benefit for post operative survival. The proposed algorithm is, to me, suggestive of a worth-based assignation to potential recipients based on age and my experience as a thoracic transplant coordinator suggest that those of a younger age are not always the patients with the longer survival, i.e. post transplant survival benefit. Many thanks for your time and consideration. Respectfully submitted, Patricia Maani, FNPC.

Committee Response:

The Subcommittee acknowledges that there are risks and other issues involved in obtaining test data by right heart catheterization. Therefore, the Subcommittee agreed that the final proposal of the system would leave the certification of right heart catheter data to the discretion of the transplant center.

As the Subcommittee continues to collect and analyze serial data on waitlisted patients, additional markers of disease severity may prove to be statistically significant in predicting waitlist urgency and post-transplant benefit. At that time, the Committee will work to incorporate those additional factors into the algorithm.

Comment 21:

vote: Oppose

I understand your reasoning,but how can you honestly be fair.All decisions will still be based on opinions,and could easily be pursuaded into bias means of allocation.You are playing with human lives here,and you are deciding up front who is going to live and who is going to die.Can you honestly say that some of the diseases won't get priority statsis?

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. There are no other factors.

Comment 22:
vote: Oppose

I was transplanted due to Alpha1 antitrypsin deficinecy, a slow genetic form of emphysema at the age of 37. Classifying recipients based on disease groups, would discriminate again those with Alpha1. We are usually young,and otherwise healthy, awesome candidates for survival, and we are generally in our 40's,giving us plenty of years to benefit from a transplant. With Alpha1, we could remain stable(but with very low lung function for months or years), yet one exacerbation of bronchitis could kill us.Many Alpha's are confined to the safe environment of their homes, so they can limit their exposure to Germs, it is intolerable to think UNOS would hand this group of people with COPD a life sentence to be home bound then die, because we aren't the sickest one today! WE may be dead tomorrow, but that doesn't count? I have seen the proposed tier system, and Alpha1 is at the bottom of priority, that is the wrong way to treat people in need of transplantation. Why don't you spend your efforts raising awareness for more donors instead? How about getting a bill passed for Uniform consent?

Committee Response:

In the course of analyzing risk factors, the Subcommittee found it useful to evaluate those risk factors based on pathophysiology. It became clear to the Subcommittee that different types of lung disease exhibit different patterns and effects. The Subcommittee then felt it legitimate to classify diseases based their similarities to each other. The disease groups are not used to pigeonhole patients or to favor any one group over another. The proposed system allocates lung based on objective criteria for each patient as measured by clinical data.

Comment 23:
vote: Oppose

I would not like to see someone like my wife who waited 3 years for a lung be passed over and over by someone who had not taken their chance like the rest of the people on the list who is to say that they did or didnot do all of the therpy, take all of the doctors orders to heart. I know that sometimes fate can be cruel, but I don't think we should put ourselfs in the of playing God any more than nessary.

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Predicted waitlist urgency and post-transplant benefit are the factors used by the algorithm, not waitlist time.

Comment 24:
vote: Oppose

If this passes there will always be someone that is near death and the ones that just need new lungs to breath and have a better life. I had a lung transplant and I was over the age limet and I have been well for 15 months, but under the new proposal they would have rejected me and I would be dead now.

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Predicted waitlist urgency and post-transplant benefit are the factors used by the algorithm, not waitlist time.

Comment 25:
vote: Oppose

If this system is going to be based on points, I profoundly oppose the 4 discriminating groups of illnesses. I am a 47 years old Alpha-1 with a 5 year old Daughter and I feel I have the same right than an IPF patient. In my opinion there should not be groups.

Committee Response:

In the course of analyzing risk factors, the Subcommittee found it useful to evaluate those risk factors based on pathophysiology. It became clear to the Subcommittee that different types of lung disease exhibit different patterns and effects. The Subcommittee then felt it legitimate to classify diseases based their similarities to each other. The disease groups are not used to pigeonhole patients or to favor any one group over another. The proposed system allocates lung based on objective criteria for each patient as measured by clinical data gathered from each individual patient.

Comment 26:
vote: Oppose

My concerns: Hospitals/Doctors would cherry Pick patients to increase survival/business stats. Money would come into play, leaving the average and less than average financial people to die. This is not a step forward it is bring back the "God Squad" Please do not do this.

Committee Response:

The proposed system allocates lung based on specific objective criteria for each patient as measured by clinical data. No other factors are considered.

Comment 27:
vote: Oppose

My husband received a double-lung transplant last July. We waited on the list for 2 years. I think that is the correct way to do it. He needed to be in the right mental and physical shape to survive the transplant. He went to respiratory rehab 5 days a week for 7 month. It made him stronger. He had to get off of several medications (narcotics) that would have hindered his recouperation. Many people wait until they're too sick to survive the surgery to make the decision. The waiting period helps them think about it and do the necessary things. It can be a sacrifice but is unfair to push someone ahead of someone who's worked so hard to get there. We lived away from our family for 9 months, maintained 2 households and were so greatful for his gift of life. People need to think about what's happening to them and take steps to help themselves.

Committee Response:

There will be a sufficient period of time until implementation of the lung allocation algorithm that will be sufficient for transplant centers to adjust to the new system, screen their patients, and enter their patient's clinical diagnostic values into the system. The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Predicted waitlist urgency and post-transplant benefit are the factors used by the algorithm, not waitlist time.

Comment 28:
vote: Oppose

OPTNS OWN STATISTICS DO NOT PROVE THAT THIS IS A WISE DECISION.THE STATISTICS THAT THERE IS A MARKED DECREASE IN THE NUMBER OF EMPHYSEMA PATIENTS FROM 41.2 PER CENT IN 1993 TO 38.8 PER CENT IN 2002 AND A LARGE INCREASE IN OTHERS,58.8 PER CENT IN 1993 TO 61.2 PER CENT IN 2002.AIA AND IPF TRANSPLANTS INCREASED FROM 21.7 PER CENT OF THE AVAILABLE LUNGS FOR TRANSPLANTS TO 35.2 PER CENT IN 2002.IN 2003 RECEIVED ONLY 29.5 PER CENT OF THE TRANSPLANTS WHILE AIA AND IPF PATIENTS RECEIVED 22.6 PER CENT.THEREFORE,CONSIDERING THESE STATISTICS I DO NOT SEE WHY THEY NEED TO PLACED IN A MORE PREVALENT LOCATION ON THE CURRENT OR FUTURE LISTS.AT THIS TIME THEY ARE AUTOMATICALLY GIVEN AND ADDITIONAL 90 DAYS WHILE OTHERS ARE NOT. THER IS TALK THAT THEIR FEVI IS LOWER THAN OTHERS.I HAVE HEARD AND READ THAT FEVI SGOULD NOT BE THE PREDICATING FACTOR IN FINAL DECISION FOR A TRANSPLANT BUT NEEDS TO BE IN CONJUNCTION WITH OTHER DATA.SOME ARE ABLE TO FUNCTION WELL AT VERY LOW FEVI LEVELS WHILE OTHERS FEEL THEY ARE SUFFOCATING. THE DEATH RATE ALONE WHILE WAITING FOR A TRANSPLANT(11.3 PER CENT)SHOWS THAT GREATER NUMBER OF COP/EMPHYSEMA PATIENTS DIE BEFORE THEY RECEIVE TRANSPLANT THAN TO ANY OTHER GROUP/GROUPS COMBINED. AFTER TRANSPLANT THE ONES THAT DO THE BEST AS FAR AS DEATH RATE ARE THE CF PATIENTS(8.3 PER CENT) AND EMPHYSEMA/COPD PATIENTS(7.9 PER CENT).THE

OTHER DESEASE GROUPS ARE NOT EVEN CLOSE TO BEING THIS LOW. I AM TOTALLY OPPOSED TO ALLOWING SOMEONE CRITICALLY ILL FROM RECEIVING SPECIAL TREATMENT,BUT THIS SHOULD NOT BE COMPLETELY BASED ON THE NATURE OF THEIR ILLNESS BUT BY THE DEGREE OF ILLNESS. I HOPE THAT THE FINAL DECISION IS NO BASED ON SPECIAL INTEREST GROUPS GETTING MEMBERS TO WRITE BUTBASED ON TRANSPLANT FIGURES,TRANSPLANT PHYSCIANS AND TRANSPLANT COORDINATORS OPINIONS.NUMBERS DO NOT ALWAYS SHOW HOW DIFFICULT IT IS FOR THE PATIENT TO SURVIVE OR TO LIVE A LIFE WITHOUT DISABILITIES.

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. There are no other factors.

Comment 29:
vote: Oppose

OPTNs own statistics do not prove that this is a wise discision. The statistics show that there is a marked decrease in the number of Emphyusema patients from 41.2% in 1993 to 38.8% in 2002) and a large increase in others (58.8% in 1993 to 61.2% in 2002). A1A and IPF transplants increased from 21.7% of the available lungs for transplant to 35.2% in 2002. In 2003,emphysema/COPD patients received only 29.5% of the transplants while A1A and IPF patients received 22.6%. This figure alone shows that these patients A1A and IPF are receiving special treatment. Therefore, considering these statistics I do not see why they need to placed in a more prevalent position on the current or future lists. At this time they are automatically given and additional 90 days while others are not. There is talk that their FEV1 is lower than others waiting and on the list. I have heard and read that FEV1 should not be the major predicating factor in final the decision for a transplant, but needs to be in conjunction with other data. Some are able to function well at very low FEV1 levels while others feel they are suffocating The death rate alone while waiting for a transplant (11.3%) shows that greater number of COPD/emphysema patients die before they receive transplant than to any other group/groups combined just by numbers alone because they are a large group. After transplant the ones that do the best as far as death rates are the CF patients (8.3%) and emphysema/COPD patients (7.9%) . The other disease groups are not even close to being this low. IPF patients are substantially lower for all periods for surviviability (Includes 3 mo, 1 yr. 3 yr and 5 yr) I am not totally opposed to allowing someone critically ill from receiving special treatment, but this should not be completely based on the nature of their illness but by the degree of illness. This degree should be applied to all on an equal basis with no special treatment for certain diseases. I hope that the final discision is not based on special interest groups or political leaders having an abundance of members lobbying this change but based on transplant figures, transplant physcians and transplant coordinators opinions. Numbers do not always show how difficult it is for the patient to survive or to live a life without disabilities.

Committee Response:

Please see response to Comment 28.

Comment 30:
vote: Oppose

Seems incredibly and unnecessarily complex, and results are likely to be somewhat subjective despite best efforts for objectivity. I have maintained for years that lung allocation based on length of time on the list was the simplest and smartest way to do it!

Committee Response:

The proposed system allocates lung based on objective criteria for each patient as measured by clinical data. Waitlist time will not be a factor. In addition, following implementation of the system, the Subcommittee will begin work on producing explanatory materials for patients and families.

Comment 31:
vote: Oppose

Selecting one illness as more important than another is unfair.

Committee Response:

In the course of analyzing risk factors, the Subcommittee found it useful to evaluate those risk factors based on pathophysiology. It became clear to the Subcommittee that different types of lung disease exhibit different patterns and effects. The Subcommittee then felt it legitimate to classify diseases based their similarities to each other. The disease groups are not used to pigeonhole patients or to favor any one group over another. The proposed system allocates lung based on objective criteria for each patient as measured by clinical data gathered from each individual patient.

Comment 32:
vote: Oppose

Sounds as if weighted by Age. Organ Transplant as of today, gives limited time, 4 -8 years? this sounds as if patient with IPF Lungs would be given first to the younger, rather than an older (50 to 60). With Limited years, each clasification should be given the same chance.

Committee Response:

Age is a factor in determining survival along with many other factors. As such, age must be considered, collectively, with other factors in allocation. However, age alone does not exclude anyone from the opportunity for a transplant under the proposed system.

Comment 33:
vote: Oppose

The currently proposed ammendments to Policy 3.7.6 is not acceptable. I believe this proposed policy based on "disease" categories unfairly discriminates against patients with Alpha-1 Anti-trypsin Deficiency. I believe(and further investigation will most likely show), that the

characteristics of COPD as contributed to, or caused by Alpha-1 are entirely different than COPD from smoking and/or advanced age. Additionally, continued enactment of this type of allocation will certainly go against public belief that a person should be on level ground for transplantation, regardless of cause of their disease or affliction causing their need for transplantation! Before this or any other lung allocation policy is enacted based on a "disease process" algorithm; more specific data relating to specific disease processes that require lung transplantation should be accumulated and the data reviewed nad better presented to the UNOS Allocation committee.

Committee Response:

In the course of analyzing risk factors, the Subcommittee found it useful to evaluate those risk factors based on pathophysiology. It became clear to the Subcommittee that different types of lung disease exhibit different patterns and effects. The Subcommittee then felt it legitimate to classify diseases based their similarities to each other. The disease groups are not used to pigeonhole patients or to favor any one group over another. The proposed system allocates lung based on objective criteria for each patient as measured by clinical data gathered from each individual patient.

Comment 34:
vote: Oppose

The philosophy behind the proposal is good and the algorithm used to determine prioroty for transplantation makes sense..the problem is the abrupt and abitrary implementation of the plan at a given date in time with no consideration given to those individuals who have been waiting for a long time and may therefore have been at the top of the list (by the previous criteria) but will now lose their advantage. A fairer way would be to transition the plan into effect in a staged manner...

Committee Response:

There will be a sufficient period of time until implementation of the lung allocation algorithm that will be sufficient for transplant centers to adjust to the new system, screen their patients, and enter their patient's clinical diagnostic values into the system.

Comment 35:
vote: Oppose

The proposed change is unfairly slanted in favor of one group. The current procedures can undoubtedly be improved, but not by this proposal. Wider input is needed if the changes are to be perceived as fair to all.

Committee Response:

The proposed lung allocation algorithm is based on survival data for all populations of lung transplant candidates. No individual patient populations are selected for priority in lung allocation.

Comment 36:
vote: Oppose

There is not enough data to support this proposal this appeeears to me to be designed by those who have a special interest in certain populations of patients

Committee Response:

The **proposed lung allocation algorithm is based on survival data for all populations of lung transplant candidates. No individual patient populations are selected for priority in lung allocation.**

Comment 37:
vote: Oppose

These comments are submitted on behalf of the Alpha-1 Association a patient advocacy and support organization representing the community of individuals affected by Alpha-1 Antitrypsin Deficiency (Alpha-1) the fourth leading cause of lung transplants. Alpha-1 is a genetic disorder that results in devastating and fatal lung disease which strikes in the prime of life (30-50 years of age). Alpha-1 afflicts an estimated 100,000 individuals in the US with fewer than 5% accurately diagnosed. As advocates for the Alpha-1 community the Association recognizes and appreciates the work done by the OPTN/UNOS Thoracic Organ Transplantation Committee to create a fair and equitable allocation system for lung transplantation. We appreciate the incorporation of public comments and additional data into the amended proposal. However, as community advocates for individuals with Alpha-1 who will require transplants and be significantly impacted by the proposed amended allocation system we believe it still fails to incorporate reasonable and constructive criteria to improve the equity of the system: 1. A provision should be added to acknowledge and meet the need for a public forum of patient end-users; 2. All patients currently on the waiting list should be grandfathered into the new allocation system; 3. Scientifically accurate serial data with a high degree of confidence in predictors should be utilized; 4. Each patient's status should be based on long term survival post transplant, severity of disease and urgency instead of - for the "sake of measurements" – disease group; 5. Inherent preference should not be given to one disease over another, nor re-transplants preference over primary ones; 6. Utility should be based on intermediate and long-term survival; 7. Timely placement on the list should be encouraged to avoid delay and adversely affect survival rates; 8. The document should be written in a language understandable by the patient/general public/layperson; 9. All allocation should be equitable from the perspective of gender, race and age; 10. The new system should have a mandatory and well defined shadow testing period of 12 months to offer choice and comparison to ensure that the new allocation system is not subjective. We understand that the current proposal is being put forth as part of the OPTN/UNOS process prior to submission to the Department of Health and Human Services (DHHS) for review and consideration. We are encouraged that OPTN/INOS is engaging in a public comment process prior to reviewing the amended allocation system at the June meeting of the Board of Directors. The Association continues to recommend that DHHS place the proposed allocation in the Federal Register to allow for formal public comments prior to implementation. In summary, we want assurances that the proposed allocation system will not be detrimental to those waiting for a transplant with a diagnosis of Alpha-1. Thank you for your consideration of these comments. Respectfully submitted, Alpha-1 Association Board of Directors Background: Alpha-1 Antitrypsin

Deficiency (Alpha-1) is one of the most prevalent, potentially lethal hereditary disorders. Discovered in 1963, Alpha-1 can cause life-threatening lung disease and/or liver disease. It is a leading genetic killer of adults in the United States. Some 1600 Alphas have received transplants in the past decade (50% lung and 50% liver) which is as many as CF. Alpha-1 is also and a leading cause of liver transplants in children. It is estimated that 20 million Americans are undetected carriers of the Alpha-1 gene and may be at risk for lung or liver disease; 100,000 individuals are actively lung or liver affected and fewer than ten percent (10,000) have been accurately diagnosed. Once receiving an accurate diagnosis individuals with Alpha-1 lung disease may receive weekly intravenous augmentation therapy made from the pooled plasma of normal donors. End stage treatment includes lung transplantation. Alpha-1 Association: The Alpha-1 Association is a member-based nonprofit organization founded to identify those affected by Alpha-1 Antitrypsin Deficiency (Alpha-1) and to improve the quality of their lives through support, education and advocacy. 1-800-521-3025

Committee Response:

The Lung Subcommittee addresses your concerns in the order they are presented:

1. **The Subcommittee has agreed to recommend a national forum to discuss the algorithm and gather feedback on its operation within the first two years of its operation.**

2. **The Subcommittee has recommended a transition period of 6 months to allow transplant centers sufficient time to review patients and enter their candidate data variables on the UNOS system for use in the lung allocation algorithm.**

3. **The lung algorithm will function using serial data on each transplant candidate.**

4. **Patient status under the proposed system is based on data for each patient. Data has shown similar survival trends among specific diagnoses, ie "disease groups." Therefore, diagnosis is taken into account in predicting urgency and survival. However, disease diagnosis is only one of many factors that are used to predict survival.**

5. **There is no preference for any one diagnosis over others. The algorithm functions based on data alone.**

6. **The Subcommittee studied one-year post-transplant survival and two-year post-transplant survival among candidates and found no statistically significant difference between the two. The Subcommittee elected to use one-year survival data for the operation of the system in the interest of being able to use more recent data to revise the system periodically.**

7. **The Subcommittee leaves the timing of determining when candidates should be listed for lung transplant to the each patient's treating physician. However, the Subcommittee strongly encourages updating waitlisted patients' data variables on the system according to the scheduled set forth in the proposal.**

8. **Once the algorithm is approved for implementation, the Subcommittee will begin work on an informative booklet for patients and their families.**

9. **The Subcommittee considered the impact of the proposed allocation algorithm on allocation among races, age groups, and genders. The Subcommittee found that the algorithm evenly distributes lungs across these groups. You are encouraged to review Figures F-1, F-2, and F-4 found in the public comment document that was released March 25, 2004.**

10. **The proposed lung allocation algorithm has already been tested on actual lung waiting lists using simulations. The Subcommittee does not feel it necessary to test it yet again.**

Comment 38:
vote: Oppose

This proposal is grossly unfair to those who suffer from other forms of lung disease and will fall through the cracks. Lung disease gradually debilitates other organs of the body. If you wait until a patient is critical his survival chances are less than those in better physical condition. Barbara Lucas

Committee Response:

The system has been designed to address all types of lung disease for which transplantation is a therapy.

Comment 39:
vote: Oppose

This proposal would lower the success rate. Lungs do not fall part over night. A patient that has not planned ahead to get listed for a transplant well in advance is less likely to be compliant post transplant. The gift of an organ from a donor should not be wasted, which is what happens if the success rate is drops as a result of this proposal.

Committee Response:

The proposal is designed to reflect changes in candidates' medical conditions, and candidate information may be updated at any time to reflect changes in condition regardless of how fast those changes may occur. In addition, transplant centers will be required to up date candidate variables at least every six months. Candidates will be offered lungs based on their urgency and survival benefit, not on the amount of time they have waited on the list.

Comment 40:
vote: Support

May 7, 2004 Public Comment United Network for Organ Sharing P.O. Box 2484 Richmond, Virginia 23218 Dear Sir or Madam: The Cystic Fibrosis Foundation is pleased that UNOS/OPTN is implementing new procedures to allocate lung donation and transplantation as first proposed in October 2003. Although we have some concerns about the impact of the changes on individuals currently awaiting transplants during the transition period to new standards, we believe that these

changes are necessary to improve equity and use of scarce resources. In the long run, we believe these standards will help all individuals with lung diseases. Overall, we are pleased with the design of the new system to balance waitlist urgency against post-transplant benefit, but we believe this scheme still could be refined and improved as it continues to have flaws. First of all, the equation regarding the lung allocation score on page 13 appears to have one of the brackets in the wrong place. We believe it should be changed as noted below. Lung Allocation Score = [(strike bracket) 100 x [(add bracket) Raw Allocation Score + (2 x 365)]/ 3 x 365 We are pleased that variables for data collection (Section I, page 18) are identified and that these will be collected at the time of listing and "at any time" deemed appropriate by the transplant team. Specific time frames should be stated for updating such data, especially so patients are not disadvantaged by less aggressive follow up. Appendix A indicates that these variables can be updated every 6 months; this should be added to the text on page 18 and in Section 3.7.6.3.2. However, updates should be more frequent than just 6-month intervals. The proposal noted the hesitation in requiring more frequent data collection primarily because of the invasiveness of the procedures. If this remains a deterrent, it would be helpful to identify alternative variables, such as those that are collected daily or weekly to chart the individual's prognosis, that would not be invasive and can provide a more accurate timely assessment to facilitate appropriate allocation. As noted on page 20, a retrospective collection of key data variables was due to be completed in April 2004, and analysis was to begin thereafter. We look forward to seeing the results of this analysis and having a period of public comment to address the impact such data collection efforts might have on this new proposal. Although it is essential to conduct regular reviews of the lung algorithm and factors affecting waitlist urgency and post-transplant survival, we do NOT believe that any changes to the policy should be made without public comment and without prior board approval. If necessary, a temporary implementation of recommendations may be considered, but only with board review. Because such changes would affect priority for lung transplants, they must be reviewed by the public and the board before being implemented in full. (See page 20, Section B, Regular and Periodic Review.) The new allocation system must allow for advances in new technologies. Just a few weeks ago, the University of Pittsburgh announced results of a study showing dramatic improvement in post-transplant survival with the use of inhaled cyclosporin. (See "Aerosol cyclosporin therapy in lung transplant recipients with bronchiolitis obliterans." Eur Respir J. 2004 Mar;23(3):384-90., Iacono AT, et al.) The proposed allocation model should take into consideration the impact of new technologies such as this on pre- and post-transplant mortality. The CF Foundation applauds changes to the allocation scheme that provide first priority for pediatric donor lungs (ages 0-11) to pediatric patients of the same age, as well as changes to allow first priority for adolescent donor lungs (ages 12-17) to adolescent patients. Also, enabling pediatric patients of all ages to have priority over adults for pediatric donor organs is helpful. Further, we are pleased that the lung allocation score shifts an emphasis overall on priority for donor organs slightly toward younger individuals for receipt of adults' organs. Although we recognize the difficulty of applying this new mechanism to pediatric patients younger than age 12, we remain concerned that this age group will continue to experience increased mortality in comparison to adults, particularly due to the lack of available organs. We encourage the committee to make it a priority to explore potential options, including alternative sources of lungs, to address this problem. We do not wish to single out pediatric patients for increasingly risky procedures; however, we believe this age group has a critical need for new options and new thinking. (CONTINUED IN NEXT NOTE)

Committee Response:

Comment 41:
vote: Support

I strongly support the changes to include urgent need for a first priorty and to give adolescent candidates priorty for adolescent donors.

Committee Response:

The Subcommittee thanks you for your support.

Comment 42:
vote: Support

(CONTINUED FROM LAST EMAIL) We believe the modified system for lung allocation will provide a more clinically and scientifically sound method for allocating lungs among all potential recipients. However, the committee should consider the impact of the use of waiting time even after the transition period. Since this was the key variable under the old system, the lung transplant community and patients may need some adjustment time for the new rules. This information may be helpful for a sense of equity, as based on the former method, particularly if more information is needed to break any ties in allocation scores in the new system. These changes are a step in the right direction and, with refinements, individuals with CF will benefit. We continue to be concerned about the potential for transplanting individuals prematurely which may result in an overall decreased lifespan. If patients can be transplanted at a time when it would be more appropriate, there is a greater chance that more patients will benefit from receipt of a transplant and have improved survival in the long run. By better determining and stratifying the health of people on the transplant list, this scheme will have a positive outcome for people with CF and other pulmonary diseases. In summary, the CF Foundation is pleased with the new measures to improve the equity of lung transplant allocation. Although the new system may be difficult during the transition for those awaiting a lung transplant, we will continue to work with families and caregivers in our community to educate them on the process and system for allocation and data collection to best ensure the future health of people with CF. We continue to offer our services to UNOS/OPTN in this process, particularly on the refinement of the scheme and data points to aid people with CF in obtaining a transplant at the optimum time to ensure their best survival. Thank you for the opportunity to comment on this critical, life-saving proposal. Please contact me or Suzanne Pattee, our Vice President of Public Policy and Patient Affairs, at 301-951-4422 with questions. Sincerely, Robert J. Beall, Ph.D. President and CEO Cystic Fibrosis Foundation 6931 Arlington Road Bethesda, Maryland 20814

Committee Response:

The Subcommittee thanks you for your support. It has agreed that the proposal will allow candidates to update their variables at any time it is necessary to reflect a change in condition. In addition, the Subcommittee has agreed to require candidates to update their variables at least one time every six months.

The Subcommittee also acknowledges and agrees that major revisions to lung allocation policy that stem from the review of the retrospective data collection project will be subject to the public comment processa dn approval by the UNOS Board of Directors.

Comment 43:
vote: Support

Anything to help get more lungs transplanted is appreciated.

Committee Response:

The Subcommittee thanks you for your support.

Comment 44:
vote: Support

As an organ donor and the parent of a child on the transplant list I strongly agree with the new policy proposals.

Committee Response:

The Subcommittee thanks you for your support.

Comment 45:
vote: Support

As Vice-chair of the Transplant Coordinators Committee, the committe met in Chicago on 4/2/04. The new thoracic policy was discussed extensively. The spirit of the new policy was stongly endorsed by all members as one way to begin overhalling the current thoracic allocation policy. Concern was voiced by the coordinators however, regarding the frequency of extending a patient's status. This was not an issue that was discussed in the new policy. Frequency of updating status, as well as the impact of this new policy on the transplant centers operating procedures needs to be addressed.

Committee Response:

The Subcommittee thanks you for your support.

Comment 46:
vote: Support

Double lung transplant recipient, 12/15/2003, Duke University Medical Center.

Committee Response:

The Subcommittee thanks you for your support.

Comment 47:
vote: Support

End-stage lung disease is very ugly. Sometimes physicians suggest to their patients that they do the transplant evaluations while they still have the energy and get on the waiting list. The patient can always turn down the transplant if they feel they do not need it. The important point is to accrue time on the list, so that when you do need the transplant you will be eligible to receive one, if all else is well. This is a good idea under the current system, but not all persons are ready to admit they need a transplant before they really do need a transplant. Additionally, at least with Cystic Fibrosis, the lung functions can decline very quickly. End-stage lung disease hits swift and fast. A patient ends up needing a double-lung transplant before they have had the time to really think about it. The waiting list is a potential death trap for them as many persons with CF find themselves in need of the transplant but not with the time to wait an average of two years. It is also a big decision for persons with CF to decide on a transplant. Many persons have a hard time coming to the realization that their lung functions have declined as they have taken pride in keeping their lung functions up to certain levels. So sometimes coming to this realization also takes up valuable and life-saving time. Please consider allocation of lungs based on the need of the patient and not by time on a waiting list. End-stage lung disease can happen so quickly, it hardly seems fair to punish people who it hits so suddenly, that they do not have two years to wait for new lungs.

Committee Response:

The Subcommittee thanks you for your support.

Comment 48:
vote: Support

How could anyone oppose a system which will provide lungs to those with the greatest need? Launi L. Mills

Committee Response:

The Subcommittee thanks you for your support.

Comment 49:
vote: Support

I am a bilateral lung transplant recipient,09/12/02. This new proposals time has come, please pass it so people will live and not die waiting. Thank you!

Committee Response:

The Subcommittee thanks you for your support.

Comment 50:
vote: Support

I am a lung transplant receipent. I was on the wait list for 2 years and could have waited longer as I was still active and able to walk on a treadmill daily. There were those who came into the transplant center where I was that needed the lung more than I.

Committee Response:

The Subcommittee thanks you for your support.

Comment 51:
vote: Support

I am a pre-transplant candidate who only has months to live. Under the current system I will not live long enough to receive a transplant, while others with less urgent need will receive transplants. I urge you to pass this proposal.

Committee Response:

The Subcommittee thanks you for your support.

Comment 52:
vote: Support

I am for this if it does not discriminate against older people who otherwise qualify

Committee Response:

The Subcommittee thanks you for your support.

Comment 53:
vote: Support

I am shocked that there is even a vote on this! How could we prioritize transplant lists ANY other way besides who is in the most immediate need first?!! When I found out the current system, I was beyond appalled...

Committee Response:

The Subcommittee thanks you for your support.

Comment 54:
vote: Support

I applaud the tremendous effort that has gone into formulating an allocation policy based upon fairly objective indices of disease severity.

Committee Response:

The Subcommittee thanks you for your support.

Comment 55:
vote: Support

I believe medical urgency and transplant benefit are better criteria for lung allocations than accrual time. Many people suffer or even die waiting for lungs because; A. Their lung disease is not diagnosed until late and therefore they do complete the testing and get wait listed until they are end-stage. B. They do not get wait listed until late in their disease due to other factors (unaware of transplant options, financial obstacles, other), and therefore when they do begin the process it is often too late. C. Their disease has been stable and then suddenly deteriorates very rapidly, not giving them enough time to go through the testing process, let alone accrue enough time on the wait list.

Committee Response:

The Subcommittee thanks you for your support.

Comment 56:
vote: Support

I believe that it is a waste of time to wait until a person is on a respirator before allowing them to have a lung transplant. These people will live a whole lot easier if they are given the transplant as soon as possible. Having them wait just makes it harder on them, because they have a greater risk of not surviving. If we know the transplant is needed, it would greatly increase the persons chance of survival if it was given them soon after.

Committee Response:

The Subcommittee thanks you for your support.

Comment 57:
vote: Support

I believe that this will significantly raise the success of lung transplant survival as the wait is a long time and deterioration plays a major factor in being healthy enough at the time of the tranplant call. Also, in order to withstand the surgery, good physical health is a plus, it is very difficult to maintain a good excersise regimend when you can't breath or are hospitalized on a vent. The sicker a person is, the more critical it is that they have transplant as soon as possible. Thank you Ginny Ortega

Committee Response:

The Subcommittee thanks you for your support.

Comment 58:
vote: Support

I believe the proposals will increase the opportunities for CF patients to have better survival rates. Thank you for your help.

Committee Response:

The Subcommittee thanks you for your support.

Comment 59:
vote: Support

I believe this is a more fair way to allocate lungs.

Committee Response:

The Subcommittee thanks you for your support.

Comment 60:
vote: Support

I believe urgency of need should have a large bearing on list placement. However, I'm not in favor of weighing survivability, as this could become a numbers game favoring the younger, fitter candidates. And there is still no guarantee of longivity even with the statistically best candidates.

Committee Response:

The Subcommittee thanks you for your support.

Comment 61:
vote: Support

I feel the current system needs to be changed. My brother and I were born with cystic fibrosis and both became candidates for transplant. I waited 28 months for my transplant, and am doing well over 2 1/2 years later. My brother died after waiting 18 months. Receiving a transplant is a miraculous gift but I hate the fact that people who smoke cigarettes are given transplants when they

ruined their own lungs. I understand that transplanting 1 lung into 2 people improves the lives of those people, however if someone must have 2 to live, they should be the priority.

Committee Response:

The Subcommittee thanks you for your support.

Comment 62:
vote: Support

I have a daughter with Cystic Fibrosis who has been told she doesn't have but about two years, so this change would most likely benefit her.

Committee Response:

The Subcommittee thanks you for your support.

Comment 63:
vote: Support

I have friends that need new lungs and do not want them to have to wait until they are too sick to handle the transplant.

Committee Response:

The Subcommittee thanks you for your support.

Comment 64:
vote: Support

I have received a double lung tx on 8/18/03 and I am doing well now. I was on the tx list over three years and I have been told that I would have gotten it sooned if this policy was in place. I have seen many not make it to there call. Also, I am avalible to volenteer if needed. I volunder and speak fore the New England Organ Bank Thank You

Committee Response:

The Subcommittee thanks you for your support.

Comment 65:
vote: Support

I Highly support this new proposed system which will provide lungs to those with the greatest need.
William Mills

Committee Response:

The Subcommittee thanks you for your support.

Comment 66:
vote: Support

I strongly support the use of Pediatric Donors for Pediatric Recipients,this has worked very well in the heart transplant population, what better hope for the donor family to know that they have helped another child not a 65 year old patient.

Committee Response:

The Subcommittee thanks you for your support.

Comment 67:
vote: Support

I strongly support this proposal.

Committee Response:

The Subcommittee thanks you for your support.

Comment 68:
vote: Support

I support letting the sickest have organs first, My hubby is very ill with lung disease

Committee Response:

The Subcommittee thanks you for your support.

Comment 69:
vote: Support

I support the OPTN/UNOS Thoracic Organ Transplantation Committee's proposal for lung allocation. My husband had a double lung transplant in February, 1993 at Barnes-Jewish Hospital in St. Louis. He was put on hold for a year from the list because he had aspergillis and then he had a

second evaluation. He was then put on the waiting list. It has been 11 years since his transplant and even though he has had rejection a few times and some complications, I feel that his benefit from the transplant outweighs any negatives. It has given him a second chance at life and we have a daughter who is now 4 years old! He was 35 years old when he received his transplant and is now going to be 46 years old in June. I support the proposal (which changes the current system) in giving priority for lung candidates most urgently in need and expected to receive the greatest survival benefit from the transplant. I believe that because my husband was so young when he had his double lung transplant (35), it definitely increased his chances for survival after the transplant. He also did not return to work after transplant which I believe has helped. Thank you.

Committee Response:

The Subcommittee thanks you for your support.

Comment 70:
vote: Support

I support the policy changes related to liver transplantation- we clearly need to balance the risk and benefit ratio in patients who are to be considered for liver transplantation, and streamline the listing process. Having a minimum MELD score for lissting is appropriate.

Committee Response:

The Subcommittee thanks you for your support.

Comment 71:
vote: Support

I support this proposal wholeheartedly. I think it may be occuring at some centers already by not listing patients (or encouraging patients not to list despite having done all testing) until they are ready to accept a transplant (as opposed to going on an inactive list if they feel they are still too early).

Committee Response:

The Subcommittee thanks you for your support.

Comment 72:
vote: Support

I support this proposed change because it would benefit the recipient because it would allocate the organ based on urgency of need. This makes more sense to me and could save many lives. I am an IPF lung transplant surviver. Thank you for your efforts, S. Storey

Committee Response:

The Subcommittee thanks you for your support.

Comment 73:
vote: Support

My father has IFP and it seems very possible he will die before receiving a lung transplant under the current system. I think that the proposed plan will better prevent people from dying unnecessarily while they wait for a lung. Obviously the real solution is to increase organ donation, but in the meantime, I think this is a necessary step. With a diagnosis like IFP it seems that a person can deteriorate very rapidly. It is important to help people when they can still be helped. Thank you for considering my comments.

Committee Response:

The Subcommittee thanks you for your support.

Comment 74:
vote: Support

Nice work. Some comments: 1. From a PH center perspective, I have concerns about using a formula for calculating probablity of post-transplant survival in patients with PPH, when there are relatively few data with which to base the calculation upon. 2. The mention of "Zones" A-D is unclear. The entire document conains the word Zone in it many times, but the term is not explained in the document 3. The nomenclature for PPH has been changed to IPAH.

Committee Response:

The Subcommittee thanks you for your support.

Comment 75:
vote: Support

People who have the greatest need (people who will not live long with-out organs)should recieve organs first. Time on the list shouldn't matter as much as medical condition.

Committee Response:

The Subcommittee thanks you for your support.

Comment 76:
vote: Support

Please vote in favor of saving lives that are in the greatest need of the organs.

Committee Response:

The Subcommittee thanks you for your support.

Comment 77:
vote: Support

Sirs: I support the new proposal of the sickest person recieving lungs the soonest. I was tx in july of '85 at Presby in Pitts by Dr. B. Griffith for eisenmengers. I was cyanotic with an arterial blood gas of a pO2 of 26mmHg on room air. my hematocrit=61.8 and had gotten up to 72. That is as about as sick as one can get. I know I would not have lived much longer. I have ben very lucky and am still doing very well. Please know that very sick people can servive tx an live for many years. Thank you, Cathy McGill ht/lg tx 1985

Committee Response:

The Subcommittee thanks you for your support.

Comment 78:
vote: Support

Sounds like an equitable plan to me. I would differ to the actural transplant physicians and their medical judgement, but all in all it would seem to be a good idea to transplant those who would be more likely to have a longer survivial than those that don't.

Committee Response:

The Subcommittee thanks you for your support.

Comment 79:
vote: Support

Thank you for considering these changes. As a double lung recipient I believe there should be some kind of "statusing" for lungs. Thanks too for giving us a chance to comment. Janice White Dbl Lung 1/17/03

Committee Response:

The Subcommittee thanks you for your support.

Comment 80:
vote: Support

The current system does not serve the needs of the patient. Each time I take my husband(who has UIP) to the pre-transplant clinic, this is painfully apparent. His condition is obviously so much worse than the others there, and yet they will receive transplants ahead of him. This is apparent to all when the others walk in on 2 lt. of oxygen and are still mobile. My husband is wheelchair bound and needs 11 lt. of oxygen at rest and 21 lt. to move around. Please change the allocation system. It truly is a matter of life and death for so many people. My husband is one of those people.

Committee Response:

The Subcommittee thanks you for your support.

Comment 81:
vote: Support

there are people suffering so bad while they just wait. I believe it should be based upon illness degree not a list.

Committee Response:

The Subcommittee thanks you for your support.

Comment 82:
vote: Support

This proposal is a significant step in the right direction to equitably allocate donor lungs. I am especially grateful to see that a system has been devised that will allow adolescent donor lungs to first be offered to waiting adolescent recipients. In heart transplantation a clear survival advantage has been demonstrated with this scheme. In addition, this will significantly increase the number of adolescents who will receive lungs while negligibly affectig the adult pool of recipients. Adolescents tend to be a disproportionately large percentage of the donor pool and yet under the old system adolescents have received a disproportionately small number of lungs. The current proposal addresses and corrects these deficiencies. The other strength of the proposal is that as new survival data comes along the algorithm can be modified. I do believe that it is important to incorporate Liou's model for CF survival into this algorithm for assessing the CF patient. Overall, I support the current proposal and urge UNOS to adopt it. Albert Faro

Committee Response:

The Subcommittee thanks you for your support.

Comment 83:
vote: Support

Too many people are dying because they started the evaluation process too late. Taking into account how sick someone is, as other organ allocation does, seems much more equitable.

Committee Response:

The Subcommittee thanks you for your support.

Comment 84:
vote: Support

We were pleased with the changes/ clarifications that UNOS has provided in this version of the policy. The lack of current data was significant enough that we had opposed the last proposal and was pleased to see that data was more current. Although the system is not perfect, the rules for allocation of lungshave been refined. The old system of "time only" was not in the best interest of many patients. The point system based on dx and prognosis post-transplantation is a positive move to a more equitable system of allocating lungs. Please let me know if you need more details.

Committee Response:

The Subcommittee thanks you for your support.

Comment 85:
vote: Support

When determining the post-transplant survival measurement, the proposal uses the survival rates at one year for all the various diagnosis groups in determining a lung allocation score. How do you incorporate the differences in survival statistics when the recipient receives a double-lung verses a single lung transplant regardless of disease? The statistics show that there is a significant survival advantage when receiving a double over a single-lung transplant five years post-transplant, whereas the 1 year survival advantage is not statistically significant, but is slightly better with a double.

Committee Response:

The Subcommittee thanks you for your support.

Comment 86:
vote: Support

Wife of single lung tx recipient UW-Madison 7/22/03 My husband could probably have waited a bit longer for a lung. Recipients who are most ill should come first, providing that a transplant will give them a reasonable chance of a quality life post transplant.

Committee Response:

The Subcommittee thanks you for your support.

Comment 87:
vote: No Opinion

I have read the entire 28 page proposal with interest and find that I cannot offer an immediate opinion due to the absence of specific critical information, namely the detail of requirements under Section 1.B.Point 6. That is the section indicating that the Committee "continues to evaluate possible requirements for periodic updates of diagnostic information for each candidate." With language such as POSSIBLE REQUIREMENTS and PERIODIC UPDATES (with no period specified)one is voting for a PIG IN A POKE at this stage of the proposal's development. Why doesn't UNOS get serious about the PAPWORTH PROTOCOL in the meanwhile and do something that will benefit ALL transplant recipients. Cordially, Rohan S. Andrew

Committee Response:

Comment 88:
vote: No Opinion

I would like to reserve my opinion on the proposal for another 12-24 months, until we see its applicability and validity. I am somewhat concerned about the repeated comments from one of the committee members that "any new system implemented is bound to be better than the waiting time system"---time will bear out whether that statement in accurate or not. As far as this specific proposal, I do not see any consideration for the RETRANSPLANTATION. How is the allocation score calculated for this population? We do have patients waiting for RETRANSPLANTATION at our center (and I am sure that is the case across the country). Please clarify this point for me as this is the second time i raise this issue and I do not see any mention of it (unless I missed reading a segment in this proposal). Moreover, it will be nice if you can give us a case illustration with 4 different patients with different characteristics (1 patient from each category A-D) and show us show the new score prioritizes them. As far as updating patient information, I think this should be optional, rather than mandatory. If it is mandatory, it means that transplant centers will incur increase costs of manpower-hours required to keep the database updated. On the contrary, if updating the parameters is optional, then a center can update the data when they deem it necessary based on the physicians follow-up testing and results (if the clinical situation dictates follow up tests).

Committee Response:

March 25, 2004

REGIONAL COMMENT SUMMARY

PROPOSAL: **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)**

Sponsoring Committee: Thoracic Committee

Description: 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.

DATE THIS DOCUMENT MODIFIED: 04/07/04

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (See Below)	Approved by Consensus	Did Not Consider
1	3/22/04			***See note below**	Conference call pending
2	5/7/04	**24 yes,** 0 no, 7 no opinion			
3				Yes * see note below	
4	4/2/04	**21 yes, 0 no, 0 no opinion**			
5	4/30/04	**16 yes,** 11 no, 6 no opinion, 3 no vote			
6	4/2/04	**44 yes,** 0 no, 9 no opinion	**50 yes,** 0 no, 3 no opinion		
7	4/23/04	**18 yes,** 0 no, 0 no opinion			
8	4/2/04	19-0-0			
9	4/21/04			*See note below	Conference call pending
10	4/30/04	**17 yes,** 1 no , 1 no opinion			
11				Yes * see note below	

COMMENTS:

Region 1: Region 1 lung transplant program representatives met via conference call on 5/5/04. There are three lung

transplant programs in the region. Two programs did not approve of the proposal as written and one did approve it. The reasons and concerns resulting in disapproval were: 1) No indication of the precision of the model; 2) Lack of clarification for dealing with statistical ties; 3) What will happen to the non-outliers, i.e. the big group in the middle- will they separate over time ; 4) Quality of life vs. survivability issues have not been addressed; 5) Does the proposal disadvantage emphysema patients; 6) Will there be the opportunity for exceptional case review?

Region 5: Although the region approved the proposal, several of the thoracic program representatives agreed that the additional data collected should be evaluated prior to implementing a policy change.

Region 6: Amendment - Initial values entered for each variable will be those used for allocation scoring. Programs may update their candidates clinical data at any time they believe a change in patient medical condition warrants such modification. All updated variables, except diagnosis, will revert to the original initial value 90 days after the update. Updates of functional status and ventilator use will revert to the original initial value 30 days after the update. Additional updates to clinical data may continue to be made as warranted by changes in the patient's medical condition.

Region 9: A conference call was held for Region 9 lung transplant program representatives. There are two lung transplant programs, and one was represented. There was general support for the proposal if the following considerations could be included: 1) Validation of the model; 2) Review of individual center lists to assess the proposal stratification of current patients; 3) Inclusion of the results of 2 recent studies(CF and Emphysema) into the model.

Region 3 & 11: The Thoracic Program Directors from Regions 3 and 11 met by conference call on Wednesday, May 12. All of the programs received a copy of the PowerPoint Presentation that was used for other regional meetings and conference calls by e-mail. The 3 and 11 Thoracic Programs also received a fax copy of the slides. Ed Garrity, MD presented the proposal. There were a few questions seeking clarification and no concerns were raised. The proposal was supported by both regions.

Re: OPTN Policy Development, Final Rule, and OPTN Long Range Planning

RESOLVED THAT when making policy recommendations to the Board of Directors regarding organ allocation, committees shall include recommendations specifically addressing the performance goals set forth in the OPTN Final Rule, including performance indicators to measure the achievement of performance goals and transplant center performance. Such performance indicators shall include baseline data evaluating how the policy being addressed is meeting the performance goals, the estimated or desired amount of improvement to be achieved by implementation of the policy as proposed, and the assessment required by the OPTN Final Rule. Committees shall make recommendations to the Board of Directors at its next regularly scheduled meeting regarding such performance goals, performance indicators, and assessments for existing policies regarding organ allocation. In doing so, committees shall take into consideration the deliberations of the strategic planning process of the OPTN.

Template for Introduction to Organ-Specific Allocation/Distribution Systems

- Would be developed separately for each organ system.

X.X **Introduction to OPTN/UNOS [*Organ*] Allocation/Distribution Policy. Objectives Statement.** The objectives of OPTN/UNOS policy for allocating/distributing [*organ*] is to [ ].

[*Considerations that may be discussed as part of the objective statement might include, for example: (1) issues of organ allocation versus distribution, (2) issues not developed fully for incorporation into policy and/or for future evaluation, and (3) factors that impact allocation/distribution that are outside the control or purview of the allocation/distribution system.*]

Compliance with OPTN Final Rule. This policy addresses requirements under the OPTN Final Rule, 42 CFR Part 121, by [ ].

[*Considerations that may be discussed as part of the Final Rule discussion include, for example:*

a. *Categories for prioritizing transplant candidates, whether they are based on medical urgency or not, and their medical basis and (reference to) supporting research and medical practice.*

b. *Any listing and de-listing criteria used in the policy, including supporting medical bases and (reference to) analyses.*

c. *Geographic unit(s) used for allocating organs, addressing how criteria such as place of patient residence or place of listing are attempted to be overcome by geographic allocation unit definition, in light of considerations including, for example, organ ischemic time, logistical matters, availability of specialized transplant and post-transplant care, and other constraints that result from available medical science.*

d. *Overall allocation protocol, demonstrating how organs are allocated according to degrees of medical urgency or other relevant categories within appropriate geographic unit(s) consistent with the following factors (if not sufficiently addressed in other sections): sound medical judgement, best use of donated organs, preservation of physician judgement in declining organ offers or use for the potential recipient, suitability for the specific organ or combination of organs, avoidance of organ wastage and futile transplants and promotion of patient access to transplantation and efficient management of organ placement, periodic review and revision as appropriate, and disassociation with candidate's place of residence or place of listing as feasible in light of the previously listed elements.*

e. *Any factors addressing issues of patient access and socio-economic equity, including how the policy addresses/reduces any ethnic barriers to transplantation, any disparities on the waiting list by ethnicity, pediatric patient access to transplantation, and any other barriers to transplantation such as those resulting from economic matters.*]

Policy Performance Measures. The impact of OPTN/UNOS policy for allocating/distributing [*organ*] and its success in meeting the objectives summarized above are evaluated periodically based upon the following performance measure(s): [ ].

[Performance measures may include, for example (but without limitation), one or more of the following: (1) risk-adjusted total life years pre- and post-transplant, (2) risk-adjusted patient and graft survival rates following transplantation, (3) risk-adjusted waiting time, (4) risk-adjusted transplantation rates, (5) days hospitalized pre- and post-transplant, (6) days in intensive care unit (ICU) pre- and post-transplant, (7) quality of life post-transplant, (8) organ ischemic time, (9) organ discard rates, and (10) organs procured per donor.]

Policy Compliance Measures. Compliance with OPTN/UNOS policy for allocating/distributing [*organ*] is assessed using processes and protocols developed by the OPTN Contractor in accordance with the contract with the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), to operate the OPTN.

3.7

Lung Allocation Policy. For the OPTN/UNOS Thoracic Organ Transplantation Committee, the overall goal of deceased-donor lung allocation policies is the ongoing development of an evidence-based allocation system that ranks each patient using objective, measurable clinical criteria such that the practice of lung transplantation increases patient benefit. In pursuing this goal, the policies should attempt to maintain or increase organ availability, preserve the public's trust in the national allocation system, and maintain a balance between justice and utility. The policy operates by employing an algorithm that incorporates clinical diagnostic variables that data suggest are predictive of the additional amount of time a patient would live on the waitlist without a transplant, (waitlist urgency) and the additional amount of time a patient would live following a lung transplant (post-transplant survival). The difference between waitlist urgency and post-transplant survival, as measured by additional days of life lived both on the waitlist and following a transplant, is predictive of transplant benefit. Lung transplant candidates are ultimately prioritized by an allocation score that is calculated to reflect the difference between transplant benefit and waitlist urgency.

The specific goals of these deceased donor lung allocation policies include:

- Reducing the number of deaths on the lung transplant waiting list;
- Increasing the transplant benefit for candidates who receive a lung transplant; and
- Ensuring the efficient and equitable allocation of lungs to active transplant candidates.

Whether lung allocation policies are approaching their goals will be assessed on an ongoing basis using data that reflect a number of metrics including but not restricted to the following:

- Waitlist death rates and post-transplant survival rates ;
- Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies;
- Risk of progression of disease;
- *[Others – or more specific breakdowns for above bullets?]*

The Committee will conduct regular reviews of the clinical diagnostic variables used, patient survival data, and the allocation mechanism itself to ensure that the lung

allocation policy is meeting the established goals. It is anticipated that the Committee will be able to evaluate the achievement of the performance goals of these lung allocation policies by reviewing on a regular basis the impact of the algorithm on both waitlist death rates and post-transplant survival rates.

Heart Allocation Policy. For the OPTN/UNOS Thoracic Organ Transplantation Committee, the overall goal of heart allocation policies is identify heart candidates who have the most urgent medical need for a transplant and who have a high likelihood of survival following the transplant and to expedite heart allocation to those candidates. In pursuing this goal, the policies should attempt to maintain or increase organ availability, preserve the public's trust in the national allocation system, and maintain a balance between justice and utility. The policy accomplishes this goal by establishing a three-tiered status system in which patients are classified by medical urgency and receive higher priority for heart offers based on higher levels of medical urgency. The allocation policies base the determination of medical urgency upon specific clinical criteria that suggest severity of illness and urgency. Candidates must meet specific criteria predictive of elevated urgency to receive the highest priority for heart allocation. Because the highest status levels are allowable for limited periods of time, transplant center must regularly re-certify a candidate's eligibility for these status levels. Fairness of the allocation mechanism is assured by Regional Review Boards that review and approve candidate's applications for listing at the elevated status levels.

The heart allocation policies use the following additional factors to prioritize heart allocation: time accumulated on the waitlist, ABO compatibility, and geography. Waiting time is accumulated by candidates at each status level to allocate organs as among other candidates at that status level. Candidates receive higher priority at each status level for ABO identical donor matches than ABO compatible donor matches. To ensure donor organ quality and reduce ischemic time, donor hearts are allocated first to candidates within local areas before being distributed to increasingly larger allocation zones.

Whether heart allocation policies are approaching their goals will be assessed on an ongoing basis using data that reflect a number of metrics including but not restricted to the following:

- Pre- and post-transplant graft and patient survival;
- Listing, transplant, death and removal rates for various patient groups (e.g., diagnostic groups, allocation score ranges, demographic and geographic groups);
- Indicators of morbidity and quality of life, as measured by available data and current methodologies;
- Risk of progression of disease;
- *[Others – or more specific breakdowns for above bullets?]*

The Committee evaluates the achievement of the performance goals of the heart allocation policy by periodically reviewing the impact of the algorithm on both waitlist death rates and post-transplant survival rates, and reviewing any additional issues that arise in relation to status determination and geographic distribution.

OPTN/UNOS Thoracic Committee
Descriptive Data Request

VAD Use in Adult Heart Waiting List Candidates and Transplant Recipients

Prepared for:
Thoracic Committee Meeting
January 23, 2004

By:
Leah Bennett Edwards
Research Department
United Network for Organ Sharing

Table of Contents

Request

Provide tabulations of VAD use by status on the waiting list and at transplant. Tabulate the time since VAD implantation for those candidates and recipients with a VAD.

Background/Purpose

The definition of Status 1A(a)(i) was modified in October 31, 2002. Prior to that time, a candidate could be listed as Status 1A for 30 days following implantation of a VAD. After the change in definition, a candidate could be listed as Status 1A for 30 days once the center felt they were medically suitable. This Committee has expressed interest in monitoring how this change affected the distribution of status on the waiting list and at transplant.

Data and Methods

For the waiting list tabulations, quarterly snapshots were examined between September 30, 2001, and December 31, 2003. Only candidates who were 18 or over at the time of listing were included. The status at the time of the snapshot was determined; in the rare case where multiple criteria were cited, the highest (first alphabetically) was used in the tabulations. Percentages were computed based on actively waiting candidates only. To examine the impact of the change in definition of Status 1A(a)(i), the results are tabulated separately before and after the modification (October 31, 2002).

For the transplant tabulations, all heart transplants performed in adult recipients between January 1, 2001, and October 31, 2003, were included.

Results

Table 1. VAD use on quarterly snapshots of the waiting list

Tabulated by Criteria

Era	Snapshot date	No VAD										Had VAD							
		Medical urgency status								All		Medical urgency status						All	
		1A - nonVAD		1B - nonVAD		2		7				1A(a) - VAD		1A(b)		1B(a)			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pre-10/31/2002	09/30/01	28	1.2	285	12.6	1823	80.5	1629	.	3765	94.3	18	0.8	27	1.2	84	3.7	129	5.7
	12/31/01	33	1.5	245	11.2	1782	81.6	1668	.	3728	94.4	26	1.2	21	1.0	76	3.5	123	5.6
	03/31/02	42	1.9	250	11.4	1775	81.0	1649	.	3716	94.3	28	1.3	16	0.7	81	3.7	125	5.7
	06/30/02	29	1.3	261	12.0	1744	80.0	1683	.	3717	93.3	25	1.1	17	0.8	103	4.7	145	6.7
	09/30/02	32	1.6	228	11.3	1634	80.8	1637	.	3531	93.7	18	0.9	18	0.9	92	4.5	128	6.3
	Average	33	1.5	254	11.7	1752	80.8	1653	.	3691	94.0	23	1.1	20	0.9	87	4.0	130	6.0
Post-10/31/2002	12/31/02	36	1.8	229	11.6	1566	79.6	1655	.	3486	93.1	32	1.6	16	0.8	88	4.5	136	6.9
	03/31/03	35	1.9	225	11.9	1499	79.6	1582	.	3341	93.4	21	1.1	15	0.8	89	4.7	125	6.6
	06/30/03	22	1.2	237	12.9	1454	79.2	1616	.	3329	93.2	23	1.3	9	0.5	92	5.0	124	6.8
	09/30/03	34	1.9	240	13.7	1355	77.4	1578	.	3207	93.1	25	1.4	15	0.9	81	4.6	121	6.9
	12/31/03	33	1.9	241	14.1	1307	76.6	1567	.	3148	92.6	14	0.8	14	0.8	98	5.7	126	7.4
	Average	32	1.8	234	12.9	1436	78.5	1600	.	3302	93.1	23	1.2	14	0.8	90	4.9	126	6.9

Table 2. VAD use at transplant

Tabulated by Criteria

Transplant date	No VAD								Had VAD							
	Medical urgency status						All		Medical urgency status						All	
	1A nonVAD		1B nonVAD		2				1A(a) - VAD		1A(b)		1B(a)			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
1/1/2001-10/31/2002	716	21.1	1036	30.6	915	27.0	2667	78.6	213	6.3	264	7.8	247	7.3	724	21.4
11/1/2002-10/31/2003	340	20.0	578	33.9	455	26.7	1373	80.6	163	9.6	82	4.8	86	5.0	331	19.4

Table 3. Survival following transplantation

Tabulated by Criteria

Transplant date	Month	Status/Criteria at Transplant																	
		1A nonVAD			1A(a) - VAD			1A(b)			1B nonVAD			1B(a)			2		
		N	# fol	Surv	N	# fol	Surv	N	# fol	Surv	N	# fol	Surv	N	# fol	Surv	N	# fol	Surv
1/1/2001-10/31/2002	1	716	636	93.2	213	181	87.2	264	231	91.0	1036	944	94.3	247	226	93.8	915	842	95.7
	3	716	599	89.6	213	165	81.3	264	223	89.4	1036	919	92.3	247	217	91.7	915	809	93.4
	6	716	584	88.1	213	158	78.3	264	212	85.8	1036	890	90.4	247	209	89.2	915	788	91.9
	9	716	566	85.8	213	153	77.3	264	205	83.8	1036	871	89.0	247	208	88.8	915	764	90.2
	12	716	426	84.2	213	119	75.2	264	169	82.5	1036	663	88.1	247	163	88.8	915	574	89.4
11/1/2002-10/31/2003	1	340	133	94.2	163	83	89.0	82	42	94.5	578	214	95.0	86	29	86.8	455	172	94.2
	3	340	38	83.8	163	25	83.4	82	14	82.8	578	87	91.8	.	.	.	455	65	90.5
	6	340	22	75.1	163	13	78.7	.	.	.	578	46	84.9	.	.	.	455	46	88.8
	9	340	19	67.9	163	12	72.7	.	.	.	578	42	83.0	.	.	.	455	37	88.8
	12	.	.	.	.	.	.	.	.	.	578	25	81.0	.	.	.	.	.	.

N = Number of transplants
 # fol = Number alive with followup
Surv = Survival rate

Request 3: Mortality Risk of Heart Transplantation for VAD Patients Compared with Remaining on the Waitlist

Purpose of Request

Compare the risk of post-transplant mortality for VAD candidates at each medical urgency status and criteria to the risk of remaining on the waiting list in that status and criteria. Determine whether patients in each status and criteria receive a transplant benefit.

Inferential Statistical Request

Analyses of VAD patients:

a) *Compute the mortality on the waiting list for VAD patients based on time since implant, for those with and without device-related complications.*
b) *Compute post-transplant mortality for recipients with a VAD based on medical urgency status and criteria (i.e., 1A(a)(i), 1A(b) and 1B(a)).*
c) *Perform a heart survival benefit analysis for patients with VADs, comparing the benefit of transplantation for Status 1A(a)(i) patients with that for Status 1B(a) patients.*

Study Population

a) Patients who were on the heart waiting list with a VAD implanted between February 1, 1999 and August 31, 2002 (cutoff to allow for at least 1 year of follow-up).
b) Patients with a VAD who received a heart transplant between February 1, 1999 and August 31, 2002 (cutoff to allow for at least 1 year of follow-up).
c) Patients who were on the heart waiting list with a VAD implanted between February 1, 1999 and August 31, 2002 (cutoff to allow for at least 1 year of follow-up).

Analytical Approach

Introduction

The question of interest here is when is the optimal time to allocate organs to VAD implant patients. The best way to answer this question would be a randomized controlled clinical trial. Death rates can be calculated from the available data for candidates while they remain in the same category (complication / no complication). However, since candidates change categories, the category specific death rates will not identify the optimal allocation strategy with certainty.

Part (c) of this request is not yet completed. The Methods and Results sections below describe the issues involved with these analyses and our progress to date.

Methods

a) Time-dependent waitlist mortality risk was analyzed for VAD patients from date of initial VAD implant to death, with follow-up censored on 7/31/2003, removal from the waitlist, or transplant. Patients who received a VAD implant before listing entered the analysis on the day of listing using left truncation. A time-dependent covariate for first complication after the VAD implant was used to estimate the risk of mortality on the waitlist with and without a complication. We identified the first complication date by the date of the first status 1A form after VAD implant date indication that device related complications with mechanical circulatory support for more than 30 day.

b) Patient survival was calculated using Cox models for heart transplant recipients with VAD implants, as time from transplant to death. Patients were followed for a maximum of three years, censoring at 8/31/03. Results are shown by group (VAD≤30 days before transplant, VAD > 30 days before transplant with complication, VAD > 30 days before transplant without complication).

c) This request requires non-standard analysis techniques which we are currently developing. We have determined that the results from various analytic approaches are very sensitive to the assumptions made in defining the analyses. We will report these results as soon as the methodology is finalized.

Results

a) Waitlist Mortality

There were 1293 patients who had a VAD implanted during February 1, 1999 - August 31, 2002 who were on the heart waiting list at the time of implantation or were listed after implantation (but before the end of the study). Of these patients, 30% (n=382) received their VAD prior to their listing date. (Of these, 12 were listed more than 4 weeks after VAD implanted, 49 were listed 2-4 weeks after VAD implanted, and 321 were listed within 2 weeks of VAD implant.)

Patients who had experienced a complication had significantly higher risk of mortality than those who had not (HR=1.94, p= 0.0006).

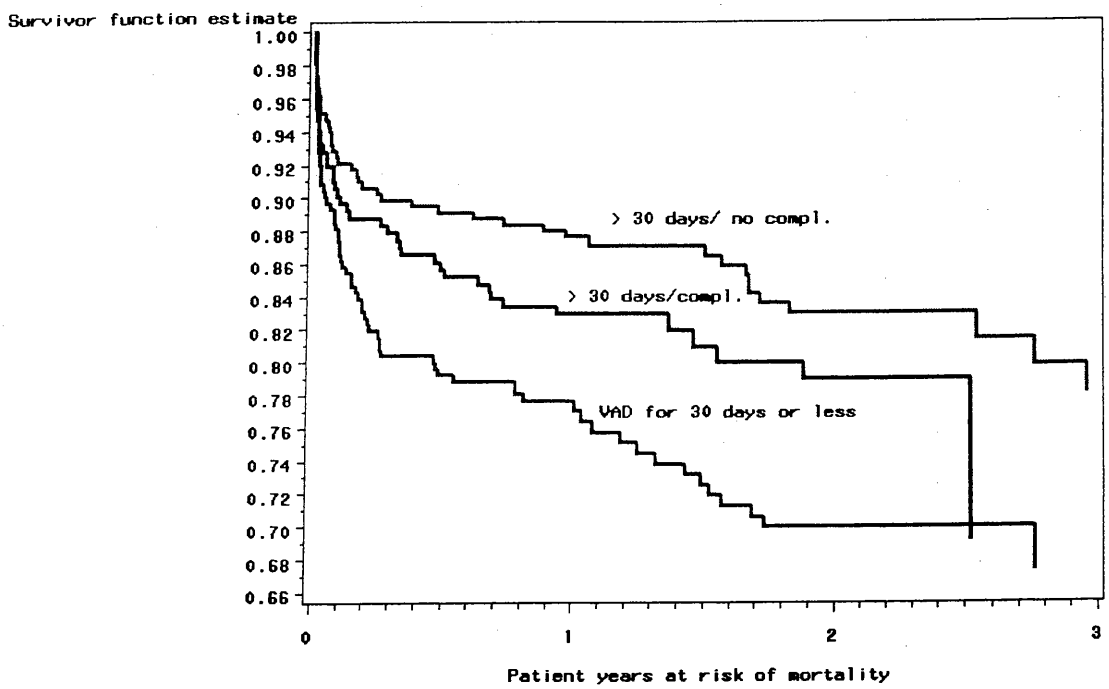
b) Post Transplant Mortality

Table 3.1 Post-Transplant Mortality Model for VAD Patients. Patients with a VAD who Received a Heart Transplant Between February 1, 1999 and August 31, 2002.

Factor (n = 783)	Percent	HR	(95% CI)	p value
VAD > 30 days/ no complications	35.4%	0.538	(0.37, 0.78)	0.0012
VAD > 30 days/ with complications	29.1%	0.714	(0.49, 1.04)	0.0818
VAD for 30 days or less	35.5%	1	Ref	

Patients who had their VAD for more than 30 days before transplant and had no complications had a significantly lower post-transplant mortality rate than those who had their VAD for 30 days or less (HR = 0.54, p = 0.001). Patients who had their VAD for more than 30 days before transplant and had complications had a marginally lower post-transplant mortality rate than those who had their VAD for 30 days or less (HR = 0.71, p = 0.082). Finally, patients who had their VAD for more than 30 days before transplant and had complications had a nonsignificantly higher post-transplant mortality rate than those who had their VAD for more than 30 days without complications (HR = 1.33, p = 0.19). Figure 3.1 shows Kaplan Meier post-transplant survival curves by VAD group.

Figure 3.1 Kaplan Meier Post-Transplant Survival Curves by VAD Group.



c) Transplant Benefit

Caveats

It is difficult to define the appropriate comparison group in this analysis because patients who went on to have complications are selectively moved to the complication group. This tends to underestimate the death rate on the waitlist with no complication and may overestimate the death rate on the waitlist with complication. We are developing a

method using time dependent Cox models that addresses these issues but it has not yet been finalized. We will report results as soon as the methodology is finalized.

It is possible that TSAM could provide another way to approach this question. Its utility however, will depend completely on the amount of data available in each category.

October 28, 2003

Matthew Coke
Policy Analyst, UNOS
International Relations and Thoracic Committees
700 N. 4th St
Richmond, VA 23219

Dear Mr. Coke:

For the past several years, to prevent wasting vital viable organs, LifeCenter Northwest (WALC), has been forced to offer thoracic organs to transplant programs in Canada. Due to the vast distance, which compromises our catchment area, (Region 6), Alaskan donors are too far away for most U.S. transplant centers to consider recovery for thoracic organs.

These offers have always been made after the U.S. donor match runs have been exhausted and time and/or distance become the only refusal reasons given. At that time, per our policy, UNOS is notified of our intention to contact Canadian centers with a specific thoracic organ offer, (these offers are limited to hearts and lungs only as abdominal organs are easily placed within the U.S.). If the offer is accepted, UNOS is immediately informed.

The centers in Vancouver and Edmonton, as well as our Donor families, are most appreciative of the opportunities they have had to transplant their recipients with organs that may not have been otherwise recovered. These programs are ultimately professional and wonderful to work with.

Prior to my assuming my current position, some efforts were initiated in order to enable LifeCenter to avoid continued non-compliance with OPTN/UNOS policies 6.4 Exportation and Importation of Organs, and 3.7 Allocation of Thoracic Organs. Subsequently, Josh Czarda advised Diana Clark, our CEO, to apply for a variance, which would recognize these special relationships with the Canadian transplant programs. After speaking with Mr. Czarda, I am writing to you to ask for your assistance in this matter.

We wish to continue to recover and place every viable organ while complying with UNOS policies. In order to achieve these two goals, please direct me to any additional steps that would facilitate approval for this variance.

Sincerely,

Lynn Cravero
Director, Clinical Services

Cc: File

EXHIBIT H

Organ Donor Center
of Hawaii

900 Fort Street Mall, Suite 1140 • Honolulu, Hawaii 96813

January 12, 2004

Aloha,

We would like to ask the UNOS Thoracic Committees' help in resolving issues that are complicating thoracic organ allocation, policy compliance, and documentation for Organ Donor Center of Hawaii (HIOP). We would like to share some facts about Hawaii and our OPO that we believe are important to take into consideration.

- Hawaii's geographic location is unique. Hawaii is the most isolated landmass in the world, surrounded by more than 2,300 miles of ocean in all directions.
- Hawaii is served by a single transplant center, St. Francis Medical Center (HISF).
- Organ Donor Center of Hawaii (HIOP – Region 6) is the smallest OPO in the United States, with a local population of 1.1 million and 17 donor hospitals spread across 4 major islands.

We are committed to maximizing the availability of organs for our local transplant candidates and those awaiting transplant on the Mainland. In order to prevent organ wastage, we make every effort to place transplantable organs when no local recipient is available. The current system for thoracic organ allocation and documentation of placement efforts is problematic for HIOP in that:

- Beyond our local area, thoracic organ match runs include all patients listed nationally, unsorted by geographic distance. (Please see attachment 1)
- If organs are to be shared successfully within the time available, HIOP coordinators must carefully examine the match run in order to locate transplant centers that are within range of acceptable cold-ischemic time & distance.
- In doing so, HIOP often 'bypasses' scores of potential recipients scattered throughout the United States, resulting in potential policy violations.
- UNET^{sm} does not allow for a center to be passed due to geographic distance. So each time HIOP performs thoracic organ placement activity a letter must be submitted to the UNOS policy compliance department explaining why the proper allocation sequence was not followed.

To alleviate these problems, HIOP would like to request that the Thoracic Committee consider the creation of new zones for thoracic organ allocation that take into account Hawaii's unique geographic location. (Please see attachment 2).

Telephone: (808) 599-7630 • FAX: (808) 599-7631 • Neighbor Islands call toll free 1 (877) 855-0603 • ODCH@aol.com • A 24 hour service

UNOS Thoracic Committee
January 12, 2004

Our suggestion is to create a sequence of allocation that would place thoracic organs locally first, then within the following zones:

Zone 'X' would extend to all transplant centers within 2,500 nm of Honolulu, HI.

Zone 'Y' would extend to all transplant centers that are beyond 2,500 nm of Honolulu, HI.

We believe this would create more 'realistic' match runs for HIOP that include only those potential recipients that are within range of acceptable cold-ischemic time & distance while excluding those who are outside these functional limits. Other factors (Status, age, waiting time) that determine the sequence of allocation would apply as usual.

We believe the potential benefits would include:

Increased speed & efficiency of thoracic organ placement.
Removal of challenges related to documentation of placement efforts.
Removal of potential policy violations.
Possible decrease in thoracic organ wastage.

No potential detriments could be identified at this time.

We genuinely appreciate your time & attention in considering these matters. We look forward to any assistance you may provide.

Sincerely,

Christopher Carroll, RN CPTC
UNOS representative (HIOP - Region 6)
Organ Donor Center of Hawaii

Attachment 1 – UNOS Heart Match Run Results of HIOP Donor

UNOS Heart Match Results

Potential Recipient Format

9/30/2002 2:50 PM

Donor Id: [redacted] **Run Number** 1 **Match Id:** [redacted] **Match Submit Date:** 9/30/2002 14:45 **Match By:** Campbell, John

Provider Information

OPO: 12P001 - HIOP - Organ Donor Center of Hawaii

Donor Hospital: 120001 - QUEENS MEDICAL CENTER

Demographic Information

Name: [redacted] **Age:** 22 **Date of Birth** **Gender:** Female

Clinical Information

Crossmatch Information: Crossmatch results used to enter 906 Refusal Codes:
None

ABO: O

Height (cm) 135 **Height (in):** 53

Weight (kg) 55 **Weight (lbs):** 121

HCV Antibody: Not Done

Hepatitis B Core Antibody Not Done

HLA: **A1:** 0 **A2:** 0 **B1:** 0 **B2:** 0

BW4: **BW6:** **CW1:** 0 **CW2:** 0

DR1: 0 **DR2:** 0

DR51: **DR52:** **DR53:**

DQ1: 0 **DQ2:** 0

Previous Gastrointestinal Disease:

Time for Preliminary Crossmatch: Yes

UNOS Heart Match Results

Donor Id: [redacted] Run Number: 1 Match Id: 148950 Match Submit Date: 9/30/2002 14:45 Match By Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs

Common OPO Status 1A ABO Primary Ped Candidates for Adolescent Donor

Common OPO Status 1A ABO Secondary Ped Candidates for Adolescent Donor

Common OPO Status 1A ABO Primary Candidates

Common OPO Status 1A ABO Secondary Candidates

Common OPO Status 1B ABO Primary Ped Candidates for Adolescent Donor

Common OPO Status 1B ABO Secondary Ped Candidates for Adolescent Donor

Common OPO Status 1B ABO Primary Candidates

Common OPO Status 1B ABO Secondary Candidates

Common OPO Status 2 ABO Primary Ped Candidates for Adolescent Donor

Common OPO Status 2 ABO Secondary Ped Candidates for Adolescent Donor

Common OPO Status 2 ABO Primary Candidates

Common OPO Status 2 ABO Secondary Candidates

Zone A Status 1A ABO Primary Ped Candidates for Adolescent Donor

Zone A Status 1A ABO Secondary Ped Candidates for Adolescent Donor

Zone A Status 1A ABO Primary Candidates

Zone A Status 1A ABO Secondary Candidates

Zone A Status 1B ABO Primary Ped Candidates for Adolescent Donor

Zone A Status 1B ABO Secondary Ped Candidates for Adolescent Donor

Zone A Status 1B ABO Primary Candidates

Zone A Status 1B ABO Secondary Candidates

Zone B Status 1A ABO Primary Ped Candidates for Adolescent Donor

Zone B Status 1A ABO Secondary Ped Candidates for Adolescent Donor

Zone B Status 1A ABO Primary Candidates

Zone B Status 1A ABO Secondary Candidates

Zone B Status 1B ABO Primary Ped Candidates for Adolescent Donor

Zone B Status 1B ABO Secondary Ped Candidates for Adolescent Donor

Zone B Status 1B ABO Primary Candidates

Zone B Status 1B ABO Secondary Candidates

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone A Status 2 ABO Primary Ped Candidates for Adolescent Donor															
Zone A Status 2 ABO Secondary Ped Candidates for Adolescent Donor															
Zone A Status 2 ABO Primary Candidates															
Zone A Status 2 ABO Secondary Candidates															
Zone B Status 2 ABO Primary Ped Candidates for Adolescent Donor															
Zone B Status 2 ABO Secondary Ped Candidates for Adolescent Donor															
Zone B Status 2 ABO Primary Candidates															
Zone B Status 2 ABO Secondary Candidates															
Zone C Status 1A ABO Primary Ped Candidates for Adolescent Donor															
Zone C Status 1A ABO Secondary Ped Candidates for Adolescent Donor															
Zone C Status 1A ABO Primary Candidates															
1	HR	WICH-TX1	[redacted]	[redacted]	(414)266-2000	16	O	0	N	N	121	304	5000	188 20:46:14	
Called:			Information:		Response:			Accept:			Ref Code:		CIT 9/2		
2	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	2	O	0	N	N	0	200	1000	181 22:43:27	
Called:			Information:		Response:			Accept:			Ref Code:				
3	HR	PACP-TX1	[redacted]	[redacted]	(215)557-8090	22	O	0	N	N	117	168	9999	114 23:51:04	
Called:			Information:		Response:			Accept:			Ref Code:				
4	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	61	O	0	N	Y	110	440	9999	74 10:52:31	
Called:			Information:		Response:			Accept:			Ref Code:				
5	HR	MAPB-TX1	[redacted]	[redacted]	(800)446-6362	58	O	0	N	Y	100	400	1500	59 15:53:10	
Called:			Information:		Response:			Accept:			Ref Code:				
6	HR	MOCG-TX1	[redacted]	[redacted]	(800)333-6432	17	O	0	N	N	110	154	3500	54 08:58:09	
Called:			Information:		Response:			Accept:			Ref Code:				
7	HR	ALUA-TX1	[redacted]	[redacted]	(800)252-3677	15	O	0	N	Y	80	180	3000	25 02:25:01	
Called:			Information:		Response:			Accept:			Ref Code:				
8	HR	LAOF-TX1	[redacted]	[redacted]	(504)842-3838	45	B	0	N	Y	112	400	1500	24 12:08:48	
Called:			Information:		Response:			Accept:			Ref Code:				
9	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	48	O	0	N	Y	100	400	1500	21 02:11:22	
Called:			Information:		Response:			Accept:			Ref Code:				
10	HR	FLJM-TX1	[redacted]	[redacted]	(305)837-5059	28	O	0	N	N	120	300	9999	16 15:46:58	
Called:			Information:		Response:			Accept:			Ref Code:				

I-6

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1A ABO Primary Candidates															
11	HR	NCBG-TX1	[redacted]	[redacted]	(800)277-7654	50	O	0	N	N	120	225	9999	14 10:32:56	
Called:			Information:	Response:	Accept:					Ref Code: 912CIT					
12	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	29	O	0	N	N	120	350	2000	12 23:40:21	
Called:			Information:	Response:	Accept:					Ref Code:					
13	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	50	O	0	N	N	50	220	2000	12 22:25:11	
Called:			Information:	Response:	Accept:					Ref Code:					
14	HR	LAOF-TX1	[redacted]	[redacted]	(504)842-3838	51	O	0	N	N	110	400	1500	05 21:27:46	
Called:			Information:	Response:	Accept:					Ref Code:					
15	HR	WASH-TX1	[redacted]	[redacted]	(888)543-3287	62	O	0	N	Y	121	331	1500	05 20:54:56	
Called:			Information:	Response:	Accept:					Ref Code:					
16	HR	MICH-TX1	[redacted]	[redacted]	(734)973-1577	12	O	0	Y	Y	100	180	1500	05 01:11:32	
Called:			Information:	Response:	Accept:					Ref Code:					
17	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	51	O	0	N	N	90	270	2000	04 23:24:06	
Called:			Information:	Response:	Accept:					Ref Code:					
18	HR	FLTG-TX1	[redacted]	[redacted]	(813)253-2640	24	O	0	N	N	92	440	1500	03 21:11:46	
Called:			Information:	Response:	Accept:					Ref Code:					
19	HR	NCDU-TX1	[redacted]	[redacted]	(252)752-5480	27	O	0	Y	N	73	400	9999	02 21:31:27	
Called:			Information:	Response:	Accept:					Ref Code:					
Zone C Status 1A ABO Secondary Candidates															
20	HR	NCDU-TX1	[redacted]	[redacted]	(252)752-5480	43	A	0	N	Y	91	400	9999	119 22:32:51	
Called:			Information:	Response:	Accept:					Ref Code:					
21	HR	OHUC-TX1	[redacted]	[redacted]	(513)558-5000	67	A	0	N	Y	105	441	9999	39 03:35:11	
Called:			Information:	Response:	Accept:					Ref Code:					
22	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	59	AB	0	N	N	100	440	2000	24 23:27:10	
Called:			Information:	Response:	Accept:					Ref Code:					
23	HR	CAUC-TX1	[redacted]	[redacted]	(310)206-6766	18	A	0	Y	Y	100	440	4000	21 20:50:30	
Called: 17:49			Information: Stephanie 18:10	Response: 18:20	Accept:					Ref Code: Donor Quality					
24	HR	CAUC-TX1	[redacted]	[redacted]	(310)206-6766	59	A	0	Y	Y	96	440	4000	19 23:46:35	
Called:			Information:	Response:	Accept:					Ref Code:					
25	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	39	AB	0	N	N	50	220	2000	12 04:03:06	
Called:			Information:	Response:	Accept:					Ref Code:					

To: Jane (HR) From: United Network for Organ Sharing

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1A ABO Secondary Candidates															
26	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	48	A	0	N	N	100	440	2000	09 23:37:06	
Called:			Information:		Response:			Accept:			Ref Code:				
27	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	56	A	0	N	Y	90	300	1500	09 20:01:50	
Called:			Information:		Response:			Accept:			Ref Code:				
28	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	64	A	0	N	N	100	400	1500	06 02:15:03	
Called:			Information:		Response:			Accept:			Ref Code:				
29	HR	NYAM-TX1	[redacted]	[redacted]	(518)262-3111	51	A	0	N	N	119	400	9999	06 02:02:51	
Called:			Information:		Response:			Accept:			Ref Code:				
30	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	53	A	0	N	N	100	440	2000	05 21:33:57	
Called:			Information:		Response:			Accept:			Ref Code:				
31	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	49	A	0	N	N	0	441	9999	05 01:19:53	
Called:			Information:		Response:			Accept:			Ref Code:				
32	HR	WIUW-TX1	[redacted]	[redacted]	(608)262-0143	44	A	0	N	N	120	350	3000	04 22:32:55	
Called:			Information:		Response:			Accept:			Ref Code:				
33	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	38	A	0	N	N	50	400	9999	03 22:18:23	LI
Called:			Information:		Response:			Accept:			Ref Code:				
34	HR	NYCP-TX1	[redacted]	[redacted]	(212)439-1370	50	A	0	N	Y	105	225	9999	03 01:19:21	
Called:			Information:		Response:			Accept:			Ref Code:				
Zone C Status 1B ABO Primary Ped Candidates for Adolescent Donor															
Zone C Status 1B ABO Secondary Ped Candidates for Adolescent Donor															
Zone C Status 1B ABO Primary Candidates															
35	HR	NEBM-TX1	[redacted]	[redacted]	(800)925-0215	59	O	0	N	N	99	350	9999	725 01:46:49	
Called:			Information:		Response:			Accept:			Ref Code:				
36	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	43	O	0	N	N	75	300	2000	659 15:18:35	
Called:			Information:		Response:			Accept:			Ref Code:				
37	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	47	O	0	N	N	100	400	9999	560 04:31:09	
Called:			Information:		Response:			Accept:			Ref Code:				
38	HR	MNUM-TX1	[redacted]	[redacted]	(800)247-4273	12	O	0	Y	Y	62	121	3000	436 20:59:02	
Called:			Information:		Response:			Accept:			Ref Code:				
39	HR	MNAN-TX1	[redacted]	[redacted]	(612)863-5700	48	O	0	Y	Y	90	250	750	393 09:32:24	
Called:			Information:		Response:			Accept:			Ref Code:				

UNOS Heart Match Results

Donor Id: [redacted] Run Number: 1 Match Id: 148950 Match Submit Date: 9/30/2002 14:45 Match By Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Primary Candidates															
40	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	55	O	0	N	N	100	400	1500	370 00:06:56	
Called:			Information:	Response:	Accept:					Ref Code:					
41	HR	CASD-TX1	[redacted]	[redacted]	(619)543-6737	41	O	0	N	Y	110	441	2000	363 03:54:18	
Called:			Information:	Response:	Accept:					Ref Code:					
42	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	66	O	0	N	N	80	200	1500	346 20:37:03	
Called:			Information:	Response:	Accept:					Ref Code:					
43	HR	CASH-TX1	[redacted]	[redacted]	(858)541-3400	34	O	0	Y	Y	90	300	1500	328 14:22:47	
Called:			Information:	Response:	Accept:					Ref Code:					
44	HR	CAPM-TX1	[redacted]	[redacted]	(415)600-1000	59	O	0	N	N	100	300	1500	314 03:04:28	
Called:			Information:	Response:	Accept:					Ref Code:					
45	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	50	O	0	Y	Y	100	400	1500	261 23:55:13	
Called:			Information:	Response:	Accept:					Ref Code:					
46	HR	FLJM-TX1	[redacted]	[redacted]	(305)837-5059	28	O	0	N	N	100	300	9999	261 21:03:42	
Called:			Information:	Response:	Accept:					Ref Code:					
47	HR	PAHM-TX1	[redacted]	[redacted]	(215)557-8090	43	O	0	N	Y	99	400	1500	241 20:37:10	KI
Called:			Information:	Response:	Accept:					Ref Code:					
48	HR	FLTO-TX1	[redacted]	[redacted]	(800)535-4483	52	O	0	N	N	0	441	1000	233 21:37:06	
Called:			Information:	Response:	Accept:					Ref Code:					
49	HR	FLTG-TX1	[redacted]	[redacted]	(813)253-2640	69	O	0	N	N	114	440	1500	205 20:01:48	
Called:			Information:	Response:	Accept:					Ref Code:					
50	HR	KYJH-TX1	[redacted]	[redacted]	(800)525-3456	59	O	0	N	N	100	250	1500	197 06:43:17	
Called:			Information:	Response:	Accept:					Ref Code:					
51	HR	MIHF-TX1	[redacted]	[redacted]	(734)973-1577	31	O	0	N	N	100	300	1500	192 22:37:43	
Called:			Information:	Response:	Accept:					Ref Code:					
52	HR	TXHS-TX1	[redacted]	[redacted]	(800)275-1744	59	O	0	N	N	100	250	9999	178 01:54:01	
Called:			Information:	Response:	Accept:					Ref Code:					
53	HR	TXSP-TX1	[redacted]	[redacted]	(800)201-0527	22	O	0	Y	Y	121	300	1500	177 20:24:20	
Called:			Information:	Response:	Accept:					Ref Code:					
54	HR	AZUA-TX1	[redacted]	[redacted]	(800)447-9477	73	O	0	N	N	101	331	1800	167 03:17:50	
Called:			Information:	Response:	Accept:					Ref Code:					
55	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	58	O	0	N	Y	100	400	1500	162 02:46:23	
Called:			Information:	Response:	Accept:					Ref Code:					

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Primary Candidates															
56	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	22	O	0	N	N	73	210	9999	156 23:21:37	
Called:			Information:		Response:		Accept:				Ref Code:				
57	HR	NEBM-TX1	[redacted]	[redacted]	(800)925-0215	65	B	0	N	N	99	350	9999	152 00:31:37	
Called:			Information:		Response:		Accept:				Ref Code:				
58	HR	KYJH-TX1	[redacted]	[redacted]	(800)525-3456	61	O	0	N	N	110	225	1500	151 22:28:47	
Called:			Information:		Response:		Accept:				Ref Code:				
59	HR	CASH-TX1	[redacted]	[redacted]	(858)541-3400	50	B	0	Y	Y	104	300	1500	144 20:07:13	
Called:			Information:		Response:		Accept:				Ref Code:				
60	HR	FLTG-TX1	[redacted]	[redacted]	(813)253-2640	52	O	0	N	N	110	440	1500	143 21:01:25	
Called:			Information:		Response:		Accept:				Ref Code:				
61	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	31	O	0	N	N	93	440	1500	137 20:21:17	
Called:			Information:		Response:		Accept:				Ref Code:				
62	HR	OHOU-TX1	[redacted]	[redacted]	(877)223-6667	42	O	0	N	N	110	441	1500	136 22:51:35	
Called:			Information:		Response:		Accept:				Ref Code:				
63	HR	WAUW-TX1	[redacted]	[redacted]	(888)543-3287	47	O	0	N	Y	99	331	1500	129 22:18:03	
Called:			Information:		Response:		Accept:				Ref Code:				
64	HR	OHOU-TX1	[redacted]	[redacted]	(877)223-6667	28	O	0	N	N	120	441	1500	126 17:16:52	
Called:			Information:		Response:		Accept:				Ref Code:				
65	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	34	B	0	N	N	100	400	1500	122 23:32:36	
Called:			Information:		Response:		Accept:				Ref Code:				
66	HR	VANG-TX1	[redacted]	[redacted]	(800)847-7831	66	B	0	N	N	100	441	3000	115 04:46:10	
Called:			Information:		Response:		Accept:				Ref Code:				
67	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	55	O	0	N	N	100	400	1500	115 00:15:37	
Called:			Information:		Response:		Accept:				Ref Code:				
68	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	27	O	0	N	Y	100	400	1500	113 05:16:46	
Called:			Information:		Response:		Accept:				Ref Code:				
69	HR	MIHF-TX1	[redacted]	[redacted]	(734)973-1577	48	O	0	N	Y	100	300	1500	109 00:12:46	
Called:			Information:		Response:		Accept:				Ref Code:				
70	HR	MIHF-TX1	[redacted]	[redacted]	(734)973-1577	53	B	0	N	N	100	300	1500	109 00:03:26	
Called:			Information:		Response:		Accept:				Ref Code:				
71	HR	MNUM-TX1	[redacted]	[redacted]	(800)247-4273	45	O	0	N	N	99	176	3500	103 02:55:53	
Called:			Information:		Response:		Accept:				Ref Code:				

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Primary Candidates															
72	HR	PAHM-TX1	[redacted]	[redacted]	(215)557-8090	62	B	0	N	N	99	400	9999	102 20:57:41	
Called:			Information:		Response:		Accept:			Ref Code:					
73	HR	PAHE-TX1	[redacted]	[redacted]	(215)557-8090	42	O	0	N	N	121	441	9999	101 18:35:46	
Called:			Information:		Response:		Accept:			Ref Code:					
74	HR	TXHD-TX1	[redacted]	[redacted]	(800)201-0527	54	O	0	N	N	102	190	9999	100 20:23:27	
Called:			Information:		Response:		Accept:			Ref Code:					
75	HR	UTLD-TX1	[redacted]	[redacted]	(800)833-6667	73	O	0	N	N	110	300	9999	94 19:51:54	
Called:			Information:		Response:		Accept:			Ref Code:					
76	HR	ARBH-TX1	[redacted]	[redacted]	(501)224-2623	57	O	0	N	N	120	180	2000	93 15:19:34	
Called:			Information:		Response:		Accept:			Ref Code:					
77	HR	PAHM-TX1	[redacted]	[redacted]	(215)557-8090	59	O	0	N	N	99	400	9999	90 04:03:12	
Called:			Information:		Response:		Accept:			Ref Code:					
78	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	52	O	0	N	N	0	441	9999	90 02:32:41	
Called:			Information:		Response:		Accept:			Ref Code:					
79	HR	TXJS-TX1	[redacted]	[redacted]	(800)201-0527	20	O	0	N	N	50	150	9999	82 22:15:51	KI
Called:			Information:		Response:		Accept:			Ref Code:					
80	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	52	O	0	N	N	85	400	9999	82 00:15:16	
Called:			Information:		Response:		Accept:			Ref Code:					
81	HR	PAHE-TX1	[redacted]	[redacted]	(215)557-8090	42	O	0	N	N	101	440	9999	81 00:19:39	
Called:			Information:		Response:		Accept:			Ref Code:					
82	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	69	O	0	N	N	75	300	2000	72 20:45:33	
Called:			Information:		Response:		Accept:			Ref Code:					
83	HR	NEBM-TX1	[redacted]	[redacted]	(800)925-0215	55	O	0	N	N	99	350	9999	70 02:33:45	
Called:			Information:		Response:		Accept:			Ref Code:					
84	HR	TXSP-TX1	[redacted]	[redacted]	(800)201-0527	35	B	0	Y	N	110	300	1500	66 09:36:17	
Called:			Information:		Response:		Accept:			Ref Code:					
85	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	53	O	0	N	N	100	440	9999	62 13:53:28	
Called:			Information:		Response:		Accept:			Ref Code:					
86	HR	TXHI-TX1	[redacted]	[redacted]	(713)737-8111	62	O	0	N	Y	100	300	2500	60 23:38:35	
Called:			Information:		Response:		Accept:			Ref Code:					
87	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	59	O	0	N	N	85	440	1500	60 22:09:44	
Called:			Information:		Response:		Accept:			Ref Code:					

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Zone C Status 1B ABO Primary Candidates

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
88	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	67	B	0	N	N	75	300	2000	60 21:54:44	
Called:			Information:		Response:		Accept:			Ref Code:					
89	HR	OHOU-TX1	[redacted]	[redacted]	(877)223-6667	34	O	0	N	N	100	200	1500	56 00:31:05	
Called:			Information:		Response:		Accept:			Ref Code:					
90	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	67	O	0	N	N	100	440	2000	49 00:13:21	
Called:			Information:		Response:		Accept:			Ref Code:					
91	HR	TXRM-TX1	[redacted]	[redacted]	(800)275-1744	57	O	0	N	N	112	400	9999	48 21:03:26	
Called:			Information:		Response:		Accept:			Ref Code:					
92	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	24	O	0	N	N	75	440	9999	46 22:18:16	
Called:			Information:		Response:		Accept:			Ref Code:					
93	HR	VANG-TX1	[redacted]	[redacted]	(800)847-7831	48	O	0	N	N	115	441	3000	45 21:39:30	
Called:			Information:		Response:		Accept:			Ref Code:					
94	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	60	O	0	N	N	100	400	1500	41 04:55:37	
Called:			Information:		Response:		Accept:			Ref Code:					
95	HR	MIHF-TX1	[redacted]	[redacted]	(734)973-1577	32	O	0	N	Y	100	300	1500	41 03:16:27	
Called:			Information:		Response:		Accept:			Ref Code:					
96	HR	MNUM-TX1	[redacted]	[redacted]	(800)247-4273	62	O	0	N	N	105	300	3500	39 22:54:07	
Called:			Information:		Response:		Accept:			Ref Code:					
97	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	62	B	0	N	N	87	440	9999	37 20:41:10	
Called:			Information:		Response:		Accept:			Ref Code:					
98	HR	NYCP-TX1	[redacted]	[redacted]	(212)439-1370	61	O	0	N	N	105	225	9999	35 05:12:58	
Called:			Information:		Response:		Accept:			Ref Code:					
99	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	58	O	0	N	N	100	440	2000	33 03:30:17	
Called:			Information:		Response:		Accept:			Ref Code:					
100	HR	MDUM-TX1	[redacted]	[redacted]	(410)242-3822	63	O	0	N	N	110	220	9999	26 21:10:20	
Called:			Information:		Response:		Accept:			Ref Code:					
101	HR	OHCC-TX1	[redacted]	[redacted]	(800)558-5433	3	O	0	N	N	0	200	1000	26 02:49:28	
Called:			Information:		Response:		Accept:			Ref Code:					
102	HR	NYMS-TX1	[redacted]	[redacted]	(212)241-7344	39	O	0	N	N	102	300	1500	25 17:14:36	
Called:			Information:		Response:		Accept:			Ref Code:					
103	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	47	B	0	N	N	100	400	9999	20 01:55:46	
Called:			Information:		Response:		Accept:			Ref Code:					

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Primary Candidates															
104	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	42	O	0	N	N	65	195	2000	19 03:37:15	
Called:			Information:		Response:		Accept:			Ref Code:					
105	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	63	O	0	N	N	100	400	9999	17 21:19:02	
Called:			Information:		Response:		Accept:			Ref Code:					
106	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	61	B	0	N	N	120	440	9999	17 20:03:35	
Called:			Information:		Response:		Accept:			Ref Code:					
107	HR	CACS-TX1	[redacted]	[redacted]	(310)423-3851	54	B	0	N	Y	100	300	2000	17 17:31:56	
Called:			Information:		Response:		Accept:			Ref Code:					
108	HR	PRCC-TX1	[redacted]	[redacted]	(787)778-5792	59	O	0	N	N	90	150	5000	16 05:12:54	
Called:			Information:		Response:		Accept:			Ref Code:					
109	HR	FLTG-TX1	[redacted]	[redacted]	(813)253-2640	62	O	0	N	N	108	440	1500	16 04:46:23	
Called:			Information:		Response:		Accept:			Ref Code:					
110	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	52	O	0	N	N	110	441	9999	12 02:13:01	
Called:			Information:		Response:		Accept:			Ref Code:					
111	HR	CAUH-TX1	[redacted]	[redacted]	(323)442-8419	55	O	0	N	N	100	300	2000	11 06:34:21	
Called:			Information:		Response:		Accept:			Ref Code:					
112	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	57	O	0	N	N	93	440	9999	07 01:26:44	
Called:			Information:		Response:		Accept:			Ref Code:					
113	HR	LAWK-TX1	[redacted]	[redacted]	(800)443-9562	65	O	0	N	Y	117	399	999	05 00:08:29	
Called:			Information:		Response:		Accept:			Ref Code:					
114	HR	VAMC-TX1	[redacted]	[redacted]	(800)847-7831	45	O	0	N	N	110	440	2500	04 21:37:53	
Called:			Information:		Response:		Accept:			Ref Code:					
115	HR	MNSM-TX1	[redacted]	[redacted]	(800)247-4273	52	O	0	N	Y	110	300	1000	04 19:51:04	
Called:			Information:		Response:		Accept:			Ref Code:					
116	HR	NYCP-TX1	[redacted]	[redacted]	(212)439-1370	65	O	0	N	N	78	168	9999	03 01:24:51	
Called:			Information:		Response:		Accept:			Ref Code:					
117	HR	VAMC-TX1	[redacted]	[redacted]	(800)847-7831	67	O	0	N	N	120	440	2500	00 02:05:49	
Called:			Information:		Response:		Accept:			Ref Code:					
Zone C Status 1B ABO Secondary Candidates															
118	HR	NYCP-TX1	[redacted]	[redacted]	(212)439-1370	58	A	1	N	Y	98	210	9999	187 18:23:08	KI
Called:			Information:		Response:		Accept:			Ref Code:					

I-13

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Secondary Candidates															
119	HR	FLJM-TX1	[redacted]	[redacted]	(305)837-5059	48	A	0	N	N	119	251	9999	156 22:50:10	
Called:			Information:		Response:		Accept:			Ref Code:					
120	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	65	A	0	Y	Y	100	400	1500	129 22:06:29	
Called:			Information:		Response:		Accept:			Ref Code:					
121	HR	ALUA-TX1	[redacted]	[redacted]	(800)252-3677	60	A	0	N	Y	120	300	3000	115 14:42:59	
Called:			Information:		Response:		Accept:			Ref Code:					
122	HR	MAPB-TX1	[redacted]	[redacted]	(800)446-6362	61	AB	0	N	Y	90	350	1500	109 21:27:01	
Called:			Information:		Response:		Accept:			Ref Code:					
123	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	58	A	0	N	N	100	400	1500	94 20:18:37	
Called:			Information:		Response:		Accept:			Ref Code:					
124	HR	WASH-TX1	[redacted]	[redacted]	(888)543-3287	59	A	0	N	N	104	265	1500	88 18:13:17	
Called:			Information:		Response:		Accept:			Ref Code:					
125	HR	NEBM-TX1	[redacted]	[redacted]	(800)925-0215	35	A	0	N	N	99	350	9999	74 20:03:28	
Called:			Information:		Response:		Accept:			Ref Code:					
126	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	49	A	0	N	N	100	400	1500	66 03:01:45	
Called:			Information:		Response:		Accept:			Ref Code:					
127	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	57	A	0	N	N	97	440	9999	60 22:40:25	
Called:			Information:		Response:		Accept:			Ref Code:					
128	HR	WISL-TX1	[redacted]	[redacted]	(414)649-3700	58	A	0	N	N	120	300	3000	59 14:39:50	
Called:			Information:		Response:		Accept:			Ref Code:					
129	HR	CASD-TX1	[redacted]	[redacted]	(619)543-6737	59	A	0	N	N	110	441	2000	54 21:16:30	
Called:			Information:		Response:		Accept:			Ref Code:					
130	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	34	A	0	N	N	75	300	2000	53 05:22:27	
Called:			Information:		Response:		Accept:			Ref Code:					
131	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	47	A	0	N	N	100	400	2500	53 02:24:10	
Called:			Information:		Response:		Accept:			Ref Code:					
132	HR	CASU-TX1	[redacted]	[redacted]	(650)723-6661	62	A	0	N	Y	100	300	2000	52 01:51:15	
Called:			Information:		Response:		Accept:			Ref Code:					
133	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	59	A	0	N	N	109	440	1500	51 21:09:19	
Called:			Information:		Response:		Accept:			Ref Code:					
134	HR	OKBC-TX1	[redacted]	[redacted]	(800)241-4483	50	A	0	N	Y	88	441	9999	51 14:48:19	
Called:			Information:		Response:		Accept:			Ref Code:					

UNOS Heart Match Results

Donor Id: [redacted] **Run Number:** 1 **Match Id:** 148950 **Match Submit Date:** 9/30/2002 14:45 **Match By** Campbell, John

Seq	WL Org	Center	Name	SSN	Telephone	Age	ABO	T X	UA	X	Weight (lbs) Min	Max	Max Mile	Wait Time D H:M:S	Other Organs
Zone C Status 1B ABO Secondary Candidates															
135	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	63	A	0	N	N	75	300	2000	48 21:16:34	
Called:			Information:	Response:	Accept:					Ref Code:					
136	HR	NYMA-TX1	[redacted]	[redacted]	(718)920-6500	67	A	0	N	N	110	280	2000	47 22:29:34	
Called:			Information:	Response:	Accept:					Ref Code:					
137	HR	MIUM-TX1	[redacted]	[redacted]	(734)973-1577	50	A	0	N	N	100	400	1500	42 01:03:13	
Called:			Information:	Response:	Accept:					Ref Code:					
138	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	58	A	0	N	N	97	300	9999	39 01:56:38	
Called:			Information:	Response:	Accept:					Ref Code:					
139	HR	MNUM-TX1	[redacted]	[redacted]	(800)247-4273	65	A	0	N	N	110	220	3500	38 01:56:46	
Called:			Information:	Response:	Accept:					Ref Code:					
140	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	57	A	0	N	N	100	200	9999	37 19:46:00	
Called:			Information:	Response:	Accept:					Ref Code:					
141	HR	CASV-TX1	[redacted]	[redacted]	(213)484-7676	71	A	0	N	N	90	200	1500	34 17:59:29	
Called:			Information:	Response:	Accept:					Ref Code:					
142	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	51	A	0	N	N	75	300	2000	31 00:17:55	
Called:			Information:	Response:	Accept:					Ref Code:					
143	HR	CASU-TX1	[redacted]	[redacted]	(650)723-6661	41	A	0	N	N	100	225	2000	30 20:42:44	
Called:			Information:	Response:	Accept:					Ref Code:					
144	HR	FLTG-TX1	[redacted]	[redacted]	(813)253-2640	19	A1	0	N	N	95	440	1500	23 17:50:10	
Called:			Information:	Response:	Accept:					Ref Code:					
145	HR	TXHS-TX1	[redacted]	[redacted]	(800)275-1744	53	A	0	N	Y	71	201	9999	20 06:39:24	
Called:			Information:	Response:	Accept:					Ref Code:					
146	HR	NJBI-TX1	[redacted]	[redacted]	(973)926-7211	58	A	0	N	N	75	300	2000	20 04:39:56	
Called:			Information:	Response:	Accept:					Ref Code:					
147	HR	PAUP-TX1	[redacted]	[redacted]	(215)557-8090	63	A	0	N	N	100	400	9999	19 22:00:01	
Called:			Information:	Response:	Accept:					Ref Code:					
148	HR	LAOF-TX1	[redacted]	[redacted]	(504)842-3838	66	A	0	N	N	110	400	1500	13 02:52:58	
Called:			Information:	Response:	Accept:					Ref Code:					
149	HR	NCDU-TX1	[redacted]	[redacted]	(252)752-5480	51	A	0	N	N	105	400	9999	12 21:35:07	
Called:			Information:	Response:	Accept:					Ref Code:					
150	HR	PATU-TX1	[redacted]	[redacted]	(215)557-8090	58	A	0	N	N	80	400	9999	12 01:52:10	
Called:			Information:	Response:	Accept:					Ref Code:					

Attachment 2 - Distance & Travel Times from Honolulu to Major U. S. Cities

From	To	Nautical Miles	Statute Miles	Kilometers
Honolulu, HI	San Francisco, CA	2,084	2,387	3,841
Honolulu, HI	Los Angeles, CA	2,217	2,551	4,105
Honolulu, HI	Portland, OR	2,254	2,594	4,174
Honolulu, HI	Seattle, WA	2,326	2,677	4,308
Honolulu, HI	Las Vegas, NV	2,393	2,754	4,431
Honolulu, HI	Phoenix, AZ	2,527	2,908	4,680
Honolulu, HI	Salt Lake City, UT	2,598	2,990	4,812
Honolulu, HI	Denver, CO	2,909	3,347	5,387
For Reference:	-	-	-	-
New York, NY	Los Angeles, CA	2,139	2,462	3,961

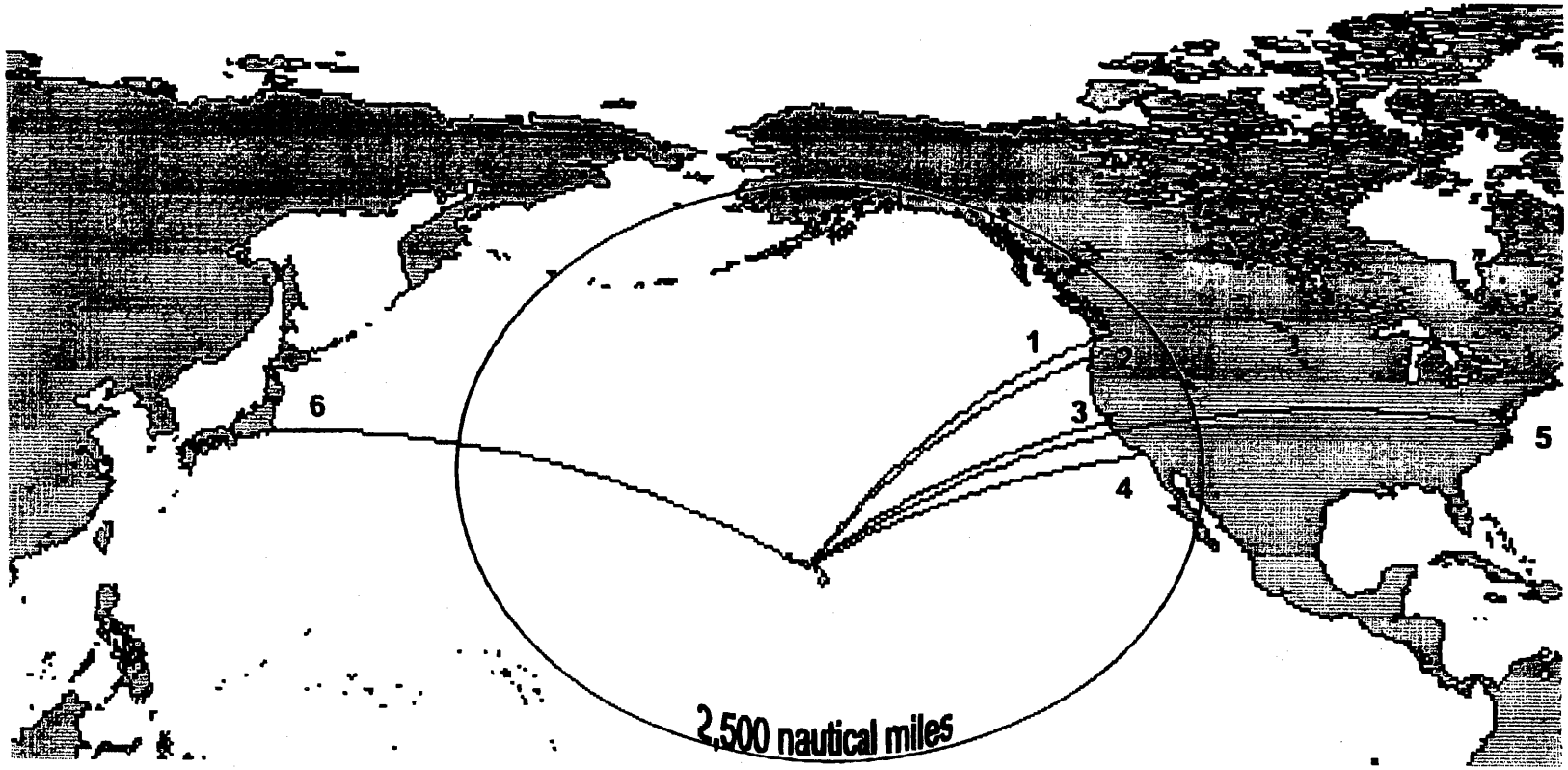
From	To	Flight Time
Honolulu, HI	San Francisco, CA	5:30
Honolulu, HI	Los Angeles, CA	5:30
Honolulu, HI	Portland, OR	5:35
Honolulu, HI	Seattle, WA	5:45
Honolulu, HI	Las Vegas, NV	6:10
Honolulu, HI	Phoenix, AZ	6:30
Honolulu, HI	Salt Lake City, UT	6:40
Honolulu, HI	Denver, CO	7:15
For Reference:	-	-
New York, NY	Los Angeles, CA	6:15

Note:
'Flight Time' indicates only the amount of time a plane spends airborne.
It does not include the one-hour 'lockout' that commercial airlines require prior to departure or ground transportation time. When sharing an organ with transplant centers on the West Coast using commercial airlines, the minimum cold ischemic time with favorable conditions is eight hours. Using charter aircraft, this time may be shortened to six hours.

Distance & Flight Time Calculations

Distances were obtained from the U.S. Geological Survey website calculator for distances & elevations in the United States available at ftp://kai.er.usgs.gov/pub/. Calculations are made using the great-circle formula. This formula assumes a spherical earth with a circle on the surface, the plane of which passes through the Earth's center. The great-circle track is the shortest distance between any two points on the surface of the Earth.

Flight times were obtained for direct flights from commercial airline timetables available on the World Wide Web.



1. Honolulu – Seattle 2,326 nm
2. Honolulu – Portland 2,254 nm
3. Honolulu – San Francisco 2,084 nm
4. Honolulu – Los Angeles 2,217 nm
5. Honolulu – UNOS (VA) 4,210 nm
6. Honolulu – Tokyo, Japan 3,318 nm

Circle on the map represents a 2,500 NM zone centered in Honolulu, HI.

Note: Organ Donor Center of Hawaii (HIOP) is physically closer to Tokyo, Japan than many transplant centers on the East Coast of the U.S.

REVIEWED AT APRIL 15, 2004, TELECONFERENCE

OPTN/UNOS Thoracic Committee
Descriptive Data Request

Heart Consent and Recovery Information for Potentially Suitable Donors

Prepared for:
Thoracic Committee meeting
January 23, 2004

By:
Leah Edwards
Research Department
United Network for Organ Sharing

Table of Contents

Committee Request

Examine the heart transplant rate by OPO for donors from whom consent for heart recovery was obtained, limited to brain-dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). Tabulate the percentage of heart transplants that were performed locally. Tabulate the number of offers made and the rank order of the acceptor for transplanted hearts.

After further discussion at the Heart Recovery and Use Subcommittee, the following additional requests were made regarding donors for whom no match was run: provide detailed medical and social history information, tabulate the other organs for which matches were run, and tabulate the other organs that were transplanted.

Background/Purpose

The percentage of donors from whom a heart was recovered and transplanted has remained relatively stable in recent years. Improving heart recovery rates has been a topic of much discussion within the Thoracic Committee. In an effort to identify potential areas of improvement, the Committee suggested that analysis should be limited to those donors that truly have potential to be heart donors, rather than examining all donors.

After the Subcommittee reviewed the original tables, additional concerns were raised regarding the donors for whom no match was run, after limiting the criteria to the most reasonable pool of potentially suitable heart donors. One concern raised during the discussion of the Subcommittee is that detailed cardiac information is not available on these donors and there may be legitimate reasons why the heart was not transplanted. By examining medical and social history characteristics, some possible contraindications to transplant could be reviewed, though there may be others that are not currently collected.

Data and Conventions

All deceased brain-dead donors between the ages of 18 and 55, who were not serologically positive (excluding CMV+) and were recovered between January 1, 2002, and June 30, 2003, were included in the analysis cohort for all tabulations.

As there are several OPOs involved in sharing arrangements for thoracic allocation (i.e., either several OPOs have a single combined local list or there is an interim allocation to other OPOs in the state after allocation to the recovering OPO but prior to allocation to Zone A), many of the tabulations make a distinction between local (OPO only) and sharing agreement (other OPOs in the state but prior to Zone A).

Summary of Results

Figure 1.

- There were 4885 donors recovered between January 1, 2002, and June 30, 2003, meeting the suitability criteria for whom consent for heart donation was obtained.
- Of these donors, the heart was transplanted in 2342 (48%).
- Of the 2543 donors in whom the heart was not transplanted, there was approximately an equal distribution between the following four group: the heart match was not run; a match was run but offer efforts were not reported; only local offers were made (include those to OPOs in a sharing arrangement) and offers were made in Zone A or beyond.

Table 1A/Figure 2A. Transplant rates within region

- The percentage of hearts from potentially suitable donors that were transplanted range across region from 39% to 55% (US rate = 48%).
- Of the heart transplants performed, there was a fairly broad range of the percentage that were performed outside the local OPO or sharing agreement of recovery. The percentage of Zone A or beyond transplants for all OPOs within a region ranged from 2% to 37%.

Table 1B/Figure 2B. Transplant rates by OPO

- The percentage of hearts from potentially suitable donors that were transplanted range across OPO from 10% to 65% (US rate = 48%).
- Of the heart transplants performed, the range of Zone A or beyond transplants by OPO ranged from 0% to 100%.

Table 2. Number of offers made for patients and to centers

- The number of potential recipients and centers for whom offers were made (Table 2) differ substantially by whether the heart was transplanted and the geographic difference of the transplant/furthest offer.

- Transplanted hearts
  - There were 2291 hearts transplanted with complete match runs available for analysis.
  - Offers to potential recipients
    - On average, the heart was accepted for the 11th potential recipient.
    - The acceptor ranged from the 1st position on the match run to the 1250th position.
    - At least half of the acceptors were in the 1st, 2nd or 3rd position on the match run.
  - Offers to centers
    - On average, offers were made to approximately 3 centers.
    - At most 105 centers were contacted for the heart to be accepted.
    - In at least half of the matches the heart was accepted by the first or second center.

- Non-transplanted hearts
  - There were 1162 non-transplanted hearts with complete match runs available for analysis.
  - Offers to potential recipients

- On average, placement efforts were stopped after offers to the 23rd potential recipient.
- The last potential recipient to whom offers were made ranged from the 1st position on the match run to the 353rd on the match run.
- In half of the matches placement efforts were discontinued prior to or at the 12th potential recipient on the match run.

o Offers to centers
- On average, placement efforts were discontinued after offers were made to 6 centers.
- At most 74 centers were contacted before placement efforts ended.
- In at least half of the match runs, offers were made to only 4 centers.

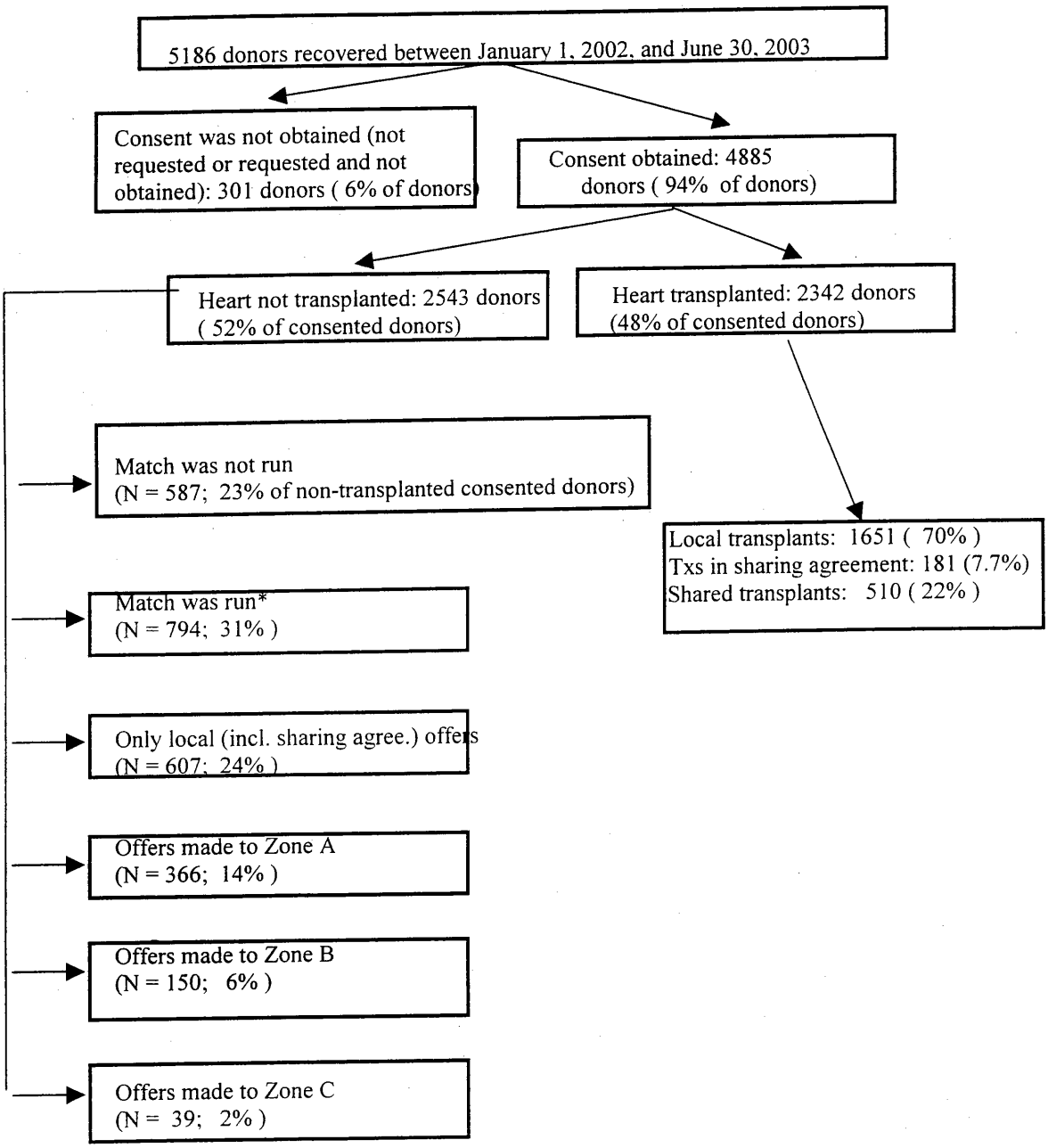
Table 3. Refusal reasons
- The distribution of refusal reasons differs considerably by whether the organ was transplanted and the geographic distance of the offers.
- For hearts that weren't transplanted for which only local or Zone A offers were made, approximately 60% were turned down for donor quality or abnormal echo results.
- The percentage of refusals for donor quality or abnormal echo were much smaller for non-transplanted hearts offered to Zone B or Zone C; in these donors, over 20% of the refusals were for donor size/weight.
- Transportation issues were much more prevalent for donors with some offers made in Zone C.
- Transplanted hearts had a much higher percentage of refusals for donor size/weight than the non-transplanted organs.
- Approximately 10% of refusals for heart transplanted locally and 18% of refusals for hearts transplanted within the sharing agreement were due to the potential recipient being ill.

Table 4. Other organs for which matches were run in donors with no heart match run
- There was only 1 donor for whom no other organ matches were run.
- The vast majority of donors had a match run for kidney.
- But the percentage of donors for whom a liver match was run was actually higher in every age group than for a kidney match.
- Approximately ¼ of the cohort had a lung match run.

Table 5. Other organs that were transplanted from donors with no heart match run
- Of the 587 donors for whom no heart match was run, only 23 had no other organs transplanted.
- Almost 80% had at least one kidney transplanted and about the same number had the liver transplanted.
- Approximately 60% of the donors had both a kidney and liver transplanted.
- Almost 1/3 of the donors had only one organ type transplanted (99 kidney, 97 liver and 1 lung).

Results

Figure 1. Utilization of hearts for donors recovered between January 1, 2002, and June 30, 2003 for brain-dead donors aged 18-55, no positive serology (Hepatitis B, Hepatitis C, HIV, HTLV or VDRL)



* Match was run but not possible to determine if offers were made or not.

Table 1A. Heart recovery information by region for deceased potentially suitable donors Recovered between January 1, 2002, and June 30, 2003*

Region	Number of donors with heart consent	Consented, not transplanted		Transplanted		Local transplants		Transplants within sharing agreement		Shared transplants	
		N	% of donors	N	% of donors	N	% of TXs	N	% of TXs	N	% of TXs
US	4885	2543	52.1%	2342	47.9%	1651	70.5%	181	7.73%	510	21.8%
1	196	97	49.5%	99	50.5%	78	78.8%	0	0%	21	21.2%
2	518	247	47.7%	271	52.3%	237	87.5%	0	0%	34	12.5%
3	779	449	57.6%	330	42.4%	170	51.5%	76	23.0%	84	25.5%
4	491	247	50.3%	244	49.7%	198	81.1%	0	0%	46	18.9%
5	724	347	47.9%	377	52.1%	275	72.9%	0	0%	102	27.1%
6	193	117	60.6%	76	39.4%	60	78.9%	0	0%	16	21.1%
7	465	263	56.6%	202	43.4%	174	86.1%	0	0%	28	13.9%
8	310	175	56.5%	135	43.5%	85	63.0%	0	0%	50	37.0%
9	236	108	45.8%	128	54.2%	69	53.9%	57	44.5%	2	1.6%
10	486	276	56.8%	210	43.2%	122	58.1%	37	17.6%	51	24.3%
11	487	217	44.6%	270	55.4%	183	67.8%	11	4.07%	76	28.1%

**Potentially suitable: brain-dead donors aged 18-55, no positive serology*

Range of % not transplanted for regions: [44.6%, 60.6%]; median across regions: 51.2%
Range of % non-local/non-sharing agreement transplants for regions: [1.6%, 37.0%]; median across regions: 21.5%

Figure 2A. Heart recovery information by region for deceased potentially suitable donors*

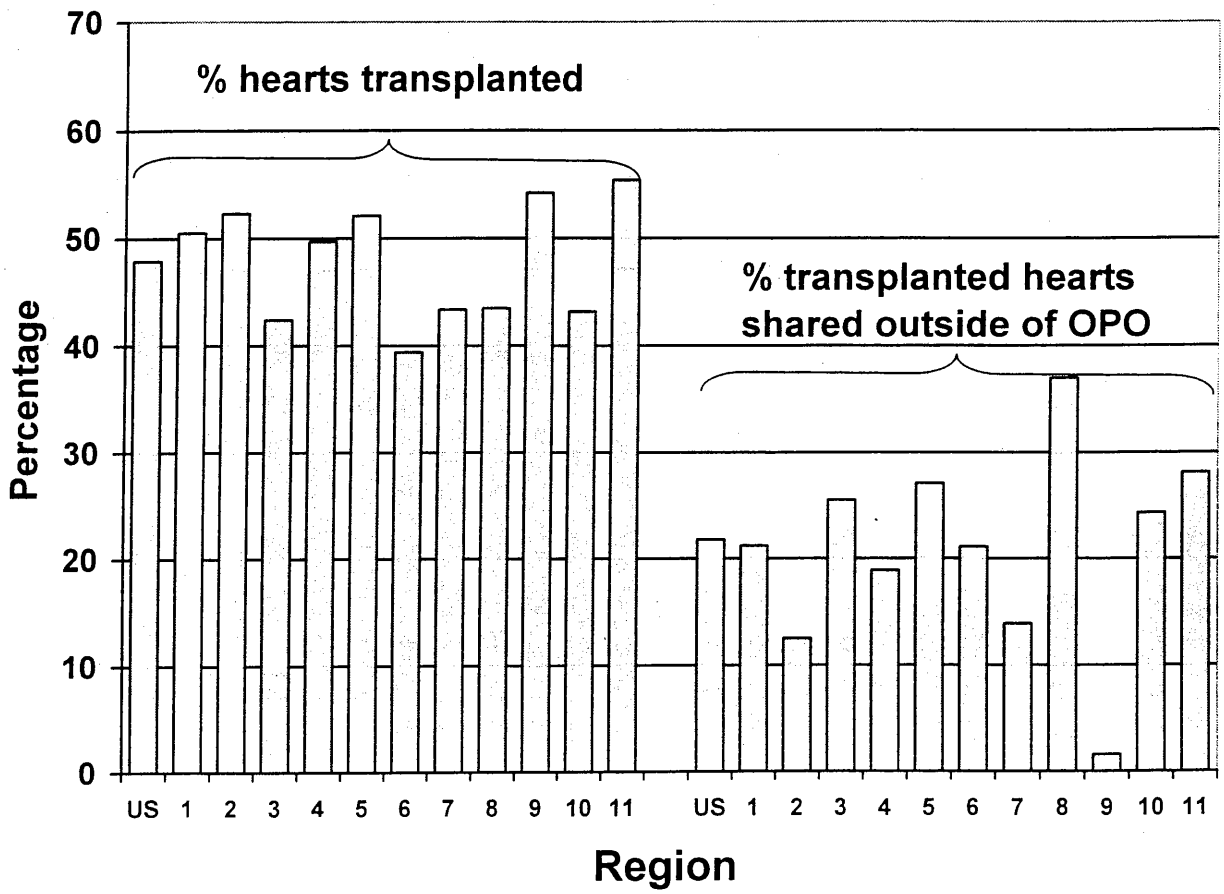


Table 1B. Heart recovery information by OPO for deceased potentially suitable donors Recovered between January 1, 2002, and June 30, 2003*

Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Hearts transplanted locally		Hearts transplanted in sharing agreement		Hearts shared and transplanted	
		N	%	N	N	N	%	N	%	N	%
US	*4885*	*2543*	*52.1%*	*2342*	*47.9%*	*1651*	*70.5%*	*181*	*7.73%*	*510*	*21.8%*
1003	116	66	56.9%	50	43.1%	43	86.0%	0	0.0%	7	14.0%
1013	32	12	37.5%	20	62.5%	14	70.0%	0	0.0%	6	30.0%
1027	41	27	65.9%	14	34.1%	4	28.6%	0	0.0%	10	71.4%
1056	82	45	54.9%	37	45.1%	27	73.0%	0	0.0%	10	27.0%
1062	26	14	53.8%	12	46.2%	3	25.0%	8	66.7%	1	8.33%
1084	204	86	42.2%	118	57.8%	111	94.1%	0	0.0%	7	5.93%
1091	84	55	65.5%	29	34.5%	27	93.1%	0	0.0%	2	6.90%
1092	113	49	43.4%	64	56.6%	30	46.9%	10	15.6%	24	37.5%
1093	46	27	58.7%	19	41.3%	13	68.4%	0	0.0%	6	31.6%
1124	52	33	63.5%	19	36.5%	3	15.8%	15	78.9%	1	5.26%
1133	45	29	64.4%	16	35.6%	14	87.5%	0	0.0%	2	12.5%
1175	131	64	48.9%	67	51.1%	63	94.0%	0	0.0%	4	5.97%
1176	73	47	64.4%	26	35.6%	22	84.6%	0	0.0%	4	15.4%
1204	74	32	43.2%	42	56.8%	22	52.4%	0	0.0%	20	47.6%
1240	27	19	70.4%	8	29.6%	0	0.0%	0	0.0%	8	100%
1254	59	25	42.4%	34	57.6%	21	61.8%	0	0.0%	13	38.2%
1274	157	84	53.5%	73	46.5%	60	82.2%	0	0.0%	13	17.8%
1285	39	19	48.7%	20	51.3%	11	55.0%	0	0.0%	9	45.0%
1305	35	24	68.6%	11	31.4%	7	63.6%	4	36.4%	0	0.0%
1309	30	19	63.3%	11	36.7%	5	45.5%	0	0.0%	6	54.5%
1359	38	23	60.5%	15	39.5%	9	60.0%	0	0.0%	6	40.0%
1369	60	36	60.0%	24	40.0%	7	29.2%	13	54.2%	4	16.7%
1377	261	121	46.4%	140	53.6%	134	95.7%	0	0.0%	6	4.29%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [35.3%, 90.5%]; median across OPOs: 53.8%
Range of % non-local/non-sharing agreement transplants for OPOs: [0%, 100%]; median across OPOs: 17.3%

Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Hearts transplanted locally		Hearts transplanted in sharing agreement		Hearts shared and transplanted	
		N	%	N	N	N	%	N	%	N	%
1380	66	38	57.6%	28	42.4%	23	82.1%	0	0.0%	5	17.9%
1388	47	23	48.9%	24	51.1%	9	37.5%	0	0.0%	15	62.5%
1391	78	50	64.1%	28	35.9%	27	96.4%	0	0.0%	1	3.57%
1393	64	39	60.9%	25	39.1%	0	0.0%	23	92.0%	2	8.00%
1395	27	14	51.9%	13	48.1%	0	0.0%	13	100%	0	0.0%
1405	154	68	44.2%	86	55.8%	63	73.3%	22	25.6%	1	1.16%
1410	83	35	42.2%	48	57.8%	41	85.4%	0	0.0%	7	14.6%
1413	29	19	65.5%	10	34.5%	8	80.0%	1	10.0%	1	10.0%
1422	78	32	41.0%	46	59.0%	34	73.9%	0	0.0%	12	26.1%
1429	159	94	59.1%	65	40.9%	41	63.1%	0	0.0%	24	36.9%
1439	63	36	57.1%	27	42.9%	11	40.7%	16	59.3%	0	0.0%
1443	157	78	49.7%	79	50.3%	67	84.8%	0	0.0%	12	15.2%
1447	48	27	56.3%	21	43.8%	17	81.0%	0	0.0%	4	19.0%
1464	67	31	46.3%	36	53.7%	32	88.9%	0	0.0%	4	11.1%
1466	45	26	57.8%	19	42.2%	14	73.7%	2	10.5%	3	15.8%
1467	84	43	51.2%	41	48.8%	26	63.4%	11	26.8%	4	9.76%
1506	113	73	64.6%	40	35.4%	37	92.5%	0	0.0%	3	7.50%
1511	67	33	49.3%	34	50.7%	25	73.5%	0	0.0%	9	26.5%
1519	94	42	44.7%	52	55.3%	43	82.7%	0	0.0%	9	17.3%
1522	47	34	72.3%	13	27.7%	12	92.3%	0	0.0%	1	7.69%
1526	173	76	43.9%	97	56.1%	78	80.4%	0	0.0%	19	19.6%
1528	73	39	53.4%	34	46.6%	28	82.4%	0	0.0%	6	17.6%
1573	29	12	41.4%	17	58.6%	3	17.6%	14	82.4%	0	0.0%
1585	17	9	52.9%	8	47.1%	1	12.5%	0	0.0%	7	87.5%
1593	132	63	47.7%	69	52.3%	46	66.7%	0	0.0%	23	33.3%
1607	98	50	51.0%	48	49.0%	39	81.3%	0	0.0%	9	18.8%
1632	53	30	56.6%	23	43.4%	22	95.7%	0	0.0%	1	4.35%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

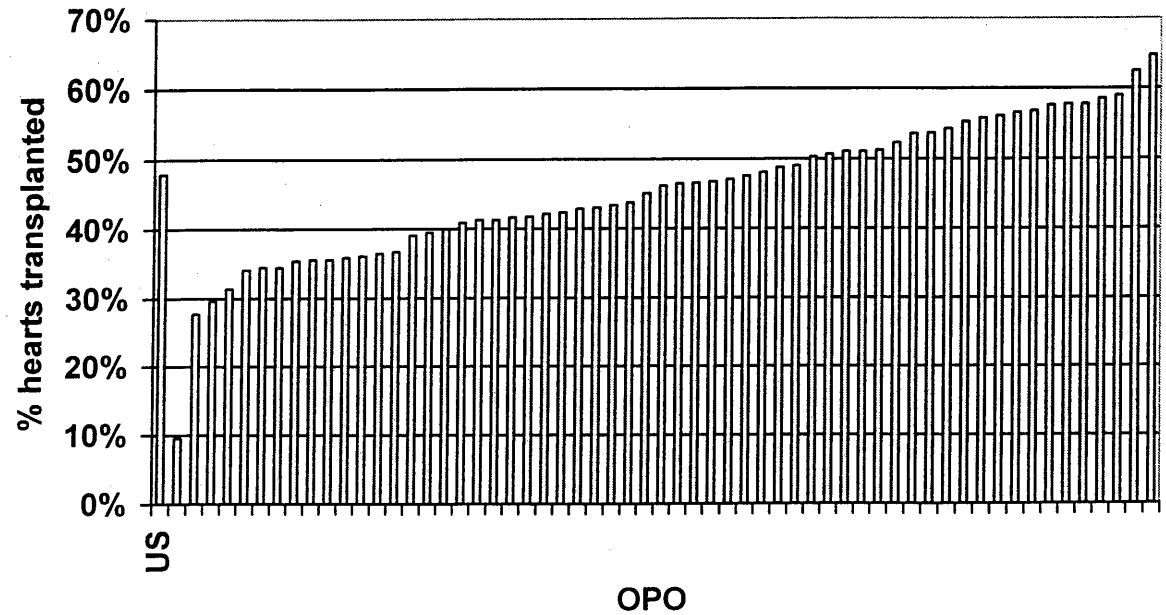
Range of % not transplanted for OPOs: [35.3%, 90.5%]; median across OPOs: 53.8%
Range of % non-local/non-sharing agreement transplants for OPOs: [0%, 100%]; median across OPOs: 17.3%

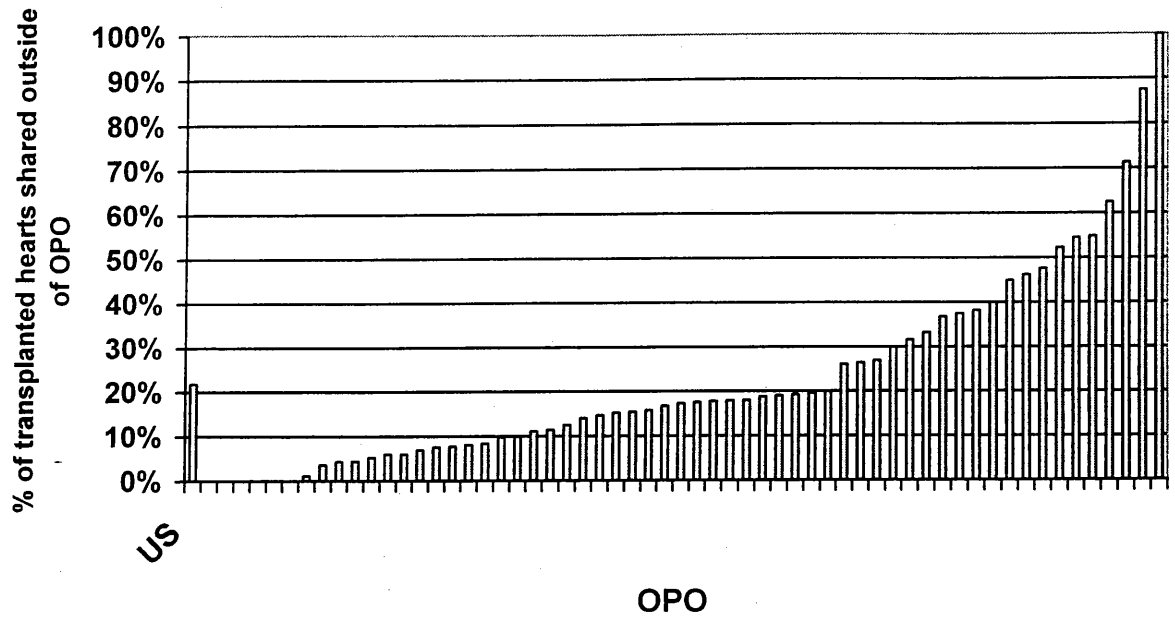
Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Hearts transplanted locally		Hearts transplanted in sharing agreement		Hearts shared and transplanted	
		N	%	N	N	N	%	N	%	N	%
1644	21	19	90.5%	2	9.52%	2	100%	0	0.0%	0	0.0%
1655	63	37	58.7%	26	41.3%	21	80.8%	0	0.0%	5	19.2%
1662	48	28	58.3%	20	41.7%	16	80.0%	0	0.0%	4	20.0%
1665	151	69	45.7%	82	54.3%	37	45.1%	0	0.0%	45	54.9%
1681	94	50	53.2%	44	46.8%	21	47.7%	0	0.0%	23	52.3%
1710	213	124	58.2%	89	41.8%	73	82.0%	0	0.0%	16	18.0%
1720	97	62	63.9%	35	36.1%	12	34.3%	19	54.3%	4	11.4%
1725	207	73	35.3%	134	64.7%	72	53.7%	0	0.0%	62	46.3%
1756	21	11	52.4%	10	47.6%	0	0.0%	10	100%	0	0.0%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [35.3%, 90.5%]; median across OPOs: 53.8%
Range of % non-local/non-sharing agreement transplants for OPOs: [0%, 100%]; median across OPOs: 17.3%

Figure 2B. Heart recovery information by OPO for deceased potentially suitable donors*





*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [35.3%, 90.5%]; median across OPOs: 53.8%
Range of % non-local/non-sharing agreement transplants for OPOs: [0%, 100%]; median across OPOs: 17.3%

Table 2. Number of offers made on each heart for which a match was run
Offers tabulate separately for potential recipients and for centers

Donor group	Offer/acceptance type	Number of hearts offered*	Offers for potential recipients				Offers to centers			
			Mean	Std. Dev.	Range	Median	Mean	Std. Dev.	Range	Median
Transplanted	Transplanted - Local	1628	4.2	8.0	[1, 134]	2	1.7	1.0	[1, 9]	1
	Transplanted – Within sharing agreement	177	3.8	6.7	[1, 67]	2	1.9	1.1	[1, 6]	2
	Transplanted – Shared (outside OPO and outside sharing agreement)	486	34.9	86.6	[1, 1250]	14	10.0	12.6	[1, 105]	6
	ALL	*2291*	*10.6*	*42.4*	*[1, 1250]*	*3*	*3.4*	*6.7*	*[1, 105]*	2
Not transplanted	Only Local offers made (may include offers within a sharing agreement)	607	16.5	22.8	[1, 226]	7	2.5	1.3	[1, 6]	2
	Zone A offers made	366	27.3	29.1	[1, 233]	17	8.0	5.0	[1, 30]	7
	Zone B offers made	150	34.2	41.2	[2, 200]	20	12.6	9.1	[2, 49]	10
	Zone C offers made	39	32.5	59.2	[1, 353]	15	16.3	15.3	[1, 74]	13
	ALL	*1162*	*22.7*	*30.3*	*[1, 353]*	*12*	*6.0*	*6.6*	*[1, 74]*	*4*

*NOTE: The number of transplanted hearts offered is slightly lower than the number of heart transplants performed primarily due to match runs with incomplete offer/refusal information.

Table 3. Refusal reasons for heart match runs

Percentage of offers by reason with reasons weighted by number of refusals per donor

Refusal reason	Not transplanted					Transplanted			
	TOTAL (N = 1154)	Only Local* offers made (N = 599)	Zone A offers made (N = 366)	Zone B offers made (N = 150)	Zone C offers made (N = 39)	TOTAL (N=1545)	TXed - Local (N = 985)	TXed - Sharing agreement (N = 112)	TXed – Shared (N = 448)
Donor Quality	41.7	45.3	43.9	30.5	9.7	12.9	10.7	12.0	18.0
Heart: Abnormal Echocardiogram	14.3	17.8	13.2	6.6	0.6	1.6	1.5	0.9	2.0
Donor Size/Weight	12.6	9.7	12.3	22.8	20.1	36.6	39.5	39.0	29.4
Abnormal Coronary Angiography	4.0	4.6	4.2	2.3	0.1	0.4	0.4	.	0.6
Heart:Test results unavail/not done/ unacceptable	4.0	4.6	4.1	1.2	3.8	1.0	0.8	0.4	1.6
Recipient testing results unavailable	2.9	0.3	4.3	9.4	4.9	3.7	1.1	3.2	9.7
Other: Other Specify	2.8	1.8	2.5	5.5	10.1	3.1	2.5	.	5.2
Operational-transportation, logistics, distance, etc	2.4	0.7	1.8	4.0	26.7	1.9	1.4	0.6	3.3
Recipient Ill	1.9	1.9	1.7	2.3	2.8	9.0	10.0	18.1	4.5
Recipient Transplanted/Inactive	1.7	1.1	1.5	2.5	9.4	5.2	5.9	4.0	4.1
Positive Crossmatch	1.6	1.8	1.3	1.9	0.2	8.0	10.9	2.3	2.9
Organ Anatomical Damage or Defect	1.4	2.4	0.5	.	0.4	0.0	.	.	0.1
Donor Social History	1.4	1.3	1.9	1.4	.	1.3	0.5	0.9	3.3
Donor Medical Urgency	1.0	0.5	1.1	3.0	1.1	1.6	0.4	.	4.5
Multiple Organ Transplant Required	1.0	0.7	1.0	1.4	2.3	1.7	1.4	4.9	1.7
Donor Age	0.9	0.6	1.2	0.9	1.4	1.6	1.3	3.0	1.7
Recipient Unavailable	0.7	0.6	0.6	1.3	2.3	2.8	3.3	0.7	2.3
Abnormal Hemodynamics	0.6	0.9	0.2	0.1	.	0.2	0.2	.	0.1
Heavy workload-program unable to accept	0.5	0.6	0.4	0.3	0.2	0.6	0.4	2.5	0.6
Positive Serological Tests	0.4	0.5	0.5	.	.	0.1	0.1	.	0.0
Patient condition improved, transplant not needed	0.4	0.2	0.6	0.8	0.7	1.8	2.1	2.0	1.0
Abnormal EKG results	0.4	0.6	0.0	0.4	.	0.1	0.0	.	0.2
Surgeon Unavailable-currently performing	0.3	0.4	0.2	0.1	0.9	1.3	0.9	1.7	2.1
HLA mismatch unacceptable	0.3	0.3	0.4	0.1	0.2	1.2	1.3	3.5	0.4
Rising Serum Transaminase	0.3	0.5	0.0	.	.	0.0	.	.	0.0

Refusal reason	Not transplanted					Transplanted			
	TOTAL (N = 1154)	Only Local* offers made (N = 599)	Zone A offers made (N = 366)	Zone B offers made (N = 150)	Zone C offers made (N = 39)	TOTAL (N=1545)	TXed - Local (N = 985)	TXed - Sharing agreement (N = 112)	TXed – Shared (N = 448)
Organ Preservation	0.3	0.3	0.1	0.3	2.1	0.0	.	.	0.1
Bypassed; another patient medically urgent	0.1	.	0.1	0.5	.	1.0	1.6	0.3	0.1
Recipient Refused	0.1	0.1	0.1	0.1	.	0.3	0.4	.	0.2
Donor ABO	0.1	0.0	0.1	.	.	0.4	0.6	.	0.1
Abnormal Blood Gases	0.0	0.0	0.0	.	.	0.2	0.3	.	0.1
Abnormal Liver Biopsy	0.0	0.0	.	.	.	0.0	0.0	.	.
Other: Multi-organ Transplant	0.0	.	0.0	.	.	0.2	0.2	.	0.3
Pulmonary: Abnormal Chest X-Ray	0.0	.	.	0.0	.	.	.	.	.
Elevated Creatinine	.	.	.	.	.	0.1	0.1	.	.
Lung test results unavailable/not done/ unacceptable	.	.	.	.	.	0.0	0.1	.	.
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

The refusal reasons of potential recipients for each donor were weighted with weights corresponding to their relative frequency. Without weighting the reasons by their relative frequency, the refusals for one donor with 1000 offers would have the same influence as 50 donors with 20 refusals each. The weights for all refusal reasons total to 1 for each donor. For example, if all of the refusals for a donor were for abnormal echo then it would have a weight of 1. But if a third of the refusals for a donor were for abnormal echo and two-thirds were for donor quality then abnormal echo would have a weight of 0.33 and donor quality would have a weight of 0.67. These weights were then averaged over the donors in each group to obtain the percentages in the table. Missing values in the table indicate that there were no refusals for that particular reason. A percentage of 0.0 indicates that there was at least one potential recipient with that refusal reason.

*NOTES:

- The number of matches for which there are refusal reasons is lower than the number for which there are matches in Table 2 due to hearts accepted on the first offer. These are primarily transplanted organs though there were 8 non-transplanted hearts that were accepted for transplant on the first offer.
- Local offers for non-transplanted hearts include offers made within the sharing agreement.

Table 4. Other organs for which matches were run for potentially suitable donors with no heart match run

Type	Matches run	Donor Age 18-35 (N = 157) N	%	36-45 (N = 146) N	%	46-55 (N = 284) N	%	All (N = 587) N	%
Organ	Intestine	23	14.6	16	11.0	32	11.3	71	12.1
	Kidney	138	87.9	134	91.8	249	87.7	521	88.8
	Liver	144	91.7	139	95.2	276	97.2	559	95.2
	Lung	39	24.8	35	24.0	84	29.6	158	26.9
	Pancreas	88	56.1	86	58.9	143	50.4	317	54.0
Organ Combination	Intestine\Kidney\Kidney-Pancreas\Liver\Lung\Pancreas	13	8.3	8	5.5	10	3.5	31	5.3
	Intestine\Kidney\Kidney-Pancreas\Liver\Pancreas	7	4.5	6	4.1	8	2.8	21	3.6
	Intestine\Kidney\Liver	.	.	.	.	6	2.1	6	1.0
	Intestine\Kidney\Liver\Lung	.	.	.	.	2	0.7	2	0.3
	Intestine\Kidney\Liver\Lung\Pancreas	.	.	1	0.7	2	0.7	3	0.5
	Intestine\Kidney\Liver\Pancreas	1	0.6	1	0.7	.	.	2	0.3
	Intestine\Liver\Lung	2	1.3	.	.	1	0.4	3	0.5
	Intestine\Liver\Lung\Pancreas	.	.	.	.	3	1.1	3	0.5
	Kidney	11	7.0	7	4.8	7	2.5	25	4.3
	Kidney-Pancreas\Liver\Lung\Pancreas	1	0.6	.	.	.	.	1	0.2
	Kidney-Pancreas\Liver\Pancreas	.	.	.	.	1	0.4	1	0.2
	Kidney\Kidney-Pancreas\Liver	.	.	3	2.1	3	1.1	6	1.0
	Kidney\Kidney-Pancreas\Liver\Lung	1	0.6	1	0.7	.	.	2	0.3
	Kidney\Kidney-Pancreas\Liver\Lung\Pancreas	16	10.2	17	11.6	39	13.7	72	12.3
	Kidney\Kidney-Pancreas\Liver\Pancreas	45	28.7	45	30.8	52	18.3	142	24.2
	Kidney\Kidney-Pancreas\Pancreas	.	.	.	.	1	0.4	1	0.2
	Kidney\Liver	39	24.8	37	25.3	82	28.9	158	26.9
	Kidney\Liver\Lung	1	0.6	3	2.1	16	5.6	20	3.4
	Kidney\Liver\Lung\Pancreas	1	0.6	1	0.7	4	1.4	6	1.0
	Kidney\Liver\Pancreas	1	0.6	4	2.7	16	5.6	21	3.6
	Kidney\Lung	1	0.6	.	.	.	.	1	0.2
	Liver	11	7.0	6	4.1	19	6.7	36	6.1
	Liver\Lung	2	1.3	3	2.1	5	1.8	10	1.7
	Liver\Lung\Pancreas	1	0.6	1	0.7	2	0.7	4	0.7
	Liver\Pancreas	2	1.3	2	1.4	5	1.8	9	1.5
	NO MATCHES RUN	**1**	**0.6**	.	.	.	.	**1**	**0.2**

Table 5. Other organs that were transplanted for potentially suitable donors with no heart match run

Type	Organs Transplanted	Donor Age						All (N = 587)	
		18-35 (N = 157)		36-45 (N = 146)		46-55 (N = 284)			
		N	%	N	%	N	%	N	%
Organ	Intestine	1	0.6	.	.	2	0.7	3	0.5
	Kidney	130	82.8	119	81.5	207	72.9	456	77.7
	Liver	128	81.5	109	74.7	223	78.5	460	78.4
	Lung	15	9.6	10	6.8	15	5.3	40	6.8
	Pancreas	34	21.7	21	14.4	11	3.9	66	11.2
Organ Combination	Kidney	25	15.9	29	19.9	45	15.8	99	16.9
	Kidney/Intestine	.	.	.	.	1	0.4	1	0.2
	Kidney/Liver	63	40.1	64	43.8	140	49.3	267	45.5
	Kidney/Liver/Intestine	1	0.6	.	.	1	0.4	2	0.3
	Kidney/Liver/Lung	8	5.1	4	2.7	8	2.8	20	3.4
	Kidney/Liver/Pancreas	29	18.5	17	11.6	10	3.5	56	9.5
	Kidney/Liver/Pancreas/Lung	4	2.5	3	2.1	1	0.4	8	1.4
	Kidney/Lung	.	.	2	1.4	1	0.4	3	0.5
	Liver	20	12.7	19	13.0	58	20.4	97	16.5
	Liver /Lung	2	1.3	1	0.7	5	1.8	8	1.4
	Liver /Pancreas	1	0.6	1	0.7	.	.	2	0.3
	Lung	1	0.6	.	.	.	.	1	0.2
	NO ORGANS TRANSPLANTED	**3**	**1.9**	**6**	**4.1**	**14**	**4.9**	**23**	**3.9**

The organ combinations shown in Table 5 are the organs that were transplanted from a donor. not the combinations of organs transplanted into an individual recipient.

Table 6A. Selected categorical donor characteristics for potentially suitable donors with no heart match run

		Donor Age						All (N = 587)	
		18-35 (N = 157)		36-45 (N = 146)		46-55 (N = 284)			
		N	%	N	%	N	%	N	%
Cause of Death	Anoxia	47	29.9	32	21.9	58	20.4	137	23.3
	Cerebrovascular/Stroke	40	25.5	86	58.9	194	68.3	320	54.5
	Head Trauma	66	42.0	26	17.8	28	9.9	120	20.4
	CNS Tumor	.	.	1	0.7	2	0.7	3	0.5
	Other	4	2.5	1	0.7	2	0.7	7	1.2
Mechanism of Death	Drowning	1	0.6	2	1.4	1	0.4	4	0.7
	Seizure	1	0.6	.	.	.	.	1	0.2
	Drug Intoxication	12	7.6	5	3.4	5	1.8	22	3.7
	Asphyxiation	9	5.7	6	4.1	3	1.1	18	3.1
	Cardiovascular	19	12.1	21	14.4	53	18.7	93	15.8
	Gunshot Wound	18	11.5	4	2.7	5	1.8	27	4.6
	Stab Wound	3	1.9	.	.	.	.	3	0.5
	Blunt Injury	38	24.2	18	12.3	19	6.7	75	12.8
	Intracranial Hemorrhage/Stroke	46	29.3	84	57.5	187	65.8	317	54.0
	Death from Natural Causes	2	1.3	4	2.7	4	1.4	10	1.7
	None of the Above	8	5.1	2	1.4	7	2.5	17	2.9
≥3 Inotropic Agents at Time of Incision		15	9.6	4	2.7	16	5.6	35	6.0
Cardiac Arrest Led to Brain Death		17	10.8	7	4.8	13	4.6	37	6.3
Cigarette Usage	History and Current Use	39	24.8	69	47.3	123	43.3	231	39.4
	History but not Current Use	5	3.2	9	6.2	26	9.2	40	6.8
	History of Use/Current Use Unknown	1	0.6	3	2.1	7	2.5	11	1.9
	None	111	70.7	65	44.5	126	44.4	302	51.4
	Usage Unknown	1	0.6	.	.	2	0.7	3	0.5
Alcohol Usage	History and Current Use	19	12.1	28	19.2	44	15.5	91	15.5
	History but not Current Use	7	4.5	9	6.2	19	6.7	35	6.0
	History of Use/Current Use Unknown	.	.	2	1.4	4	1.4	6	1.0
	None	130	82.8	106	72.6	214	75.4	450	76.7
	Usage Unknown	1	0.6	1	0.7	3	1.1	5	0.9

		Donor Age						All (N = 587)	
		18-35 (N = 157)		36-45 (N = 146)		46-55 (N = 284)			
		N	%	N	%	N	%	N	%
IV Drug Usage	**History and Current Use**	4	2.5	2	1.4	.	.	6	1.0
	History but not Current Use	5	3.2	.	.	1	0.4	6	1.0
	History of Use/Current Use Unknown	.	.	2	1.4	.	.	2	0.3
	None	146	93.0	141	96.6	282	99.3	569	96.9
	Usage Unknown	2	1.3	1	0.7	1	0.4	4	0.7
Cocaine Usage	**History and Current Use**	12	7.6	12	8.2	9	3.2	33	5.6
	History but not Current Use	5	3.2	11	7.5	10	3.5	26	4.4
	History of Use/Current Use Unknown	6	3.8	5	3.4	2	0.7	13	2.2
	None	129	82.2	115	78.8	262	92.3	506	86.2
	Usage Unknown	5	3.2	3	2.1	1	0.4	9	1.5
Other Drug Usage	**History and Current Use**	42	26.8	21	14.4	21	7.4	84	14.3
	History but not Current Use	13	8.3	16	11.0	22	7.7	51	8.7
	History of Use/Current Use Unknown	8	5.1	4	2.7	3	1.1	15	2.6
	None	91	58.0	101	69.2	237	83.5	429	73.1
	Usage Unknown	3	1.9	4	2.7	1	0.4	8	1.4
Insulin dependency	**No**	1	0.6	5	3.4	27	9.5	33	5.6
	Insulin Dependent Diabetes	2	1.3	4	2.7	7	2.5	13	2.2
	Non-Insulin Dependent Diabetes	2	1.3	1	0.7	3	1.1	6	1.0
	Diabetes, Dependency Unknown	3	1.9	4	2.7	8	2.8	15	2.6
	Unknown	1	0.6	1	0.7	4	1.4	6	1.0
	Not applicable (No Diabetes or Unknown Diabetes status)	148	94.3	131	89.7	235	82.7	514	87.6
History of Hypertension	**N**	136	86.6	91	62.3	126	44.4	353	60.1
	Y	21	13.4	54	37.0	154	54.2	229	39.0
	U	.	.	1	0.7	4	1.4	5	0.9
Lifestyle Factors	**No Lifestyle Factors reported**	85	54.1	100	68.5	225	79.2	410	69.8
	Other	4	2.5	3	2.1	2	0.7	9	1.5
	Prison	5	3.2	9	6.2	11	3.9	25	4.3
	Prison/Other	1	0.6	1	0.7	1	0.4	3	0.5
	Prison/Sexual Promiscuity	1	0.6	1	0.7	1	0.4	3	0.5
	Prison/Tattoos	11	7.0	6	4.1	1	0.4	18	3.1

		Donor Age						All (N = 587)	
		18-35 (N = 157)		36-45 (N = 146)		46-55 (N = 284)			
		N	%	N	%	N	%	N	%
	Prison/Tattoos/Other	2	1.3	.	.	.	.	2	0.3
	Prison/Tattoos/Sexual Promiscuity	1	0.6	.	.	.	.	1	0.2
	Sexual Promiscuity	.	.	.	.	1	0.4	1	0.2
	Tattoos	35	22.3	10	6.8	18	6.3	63	10.7
	Tattoos/Other	3	1.9	4	2.7	1	0.4	8	1.4
	Unknown	9	5.7	12	8.2	23	8.1	44	7.5
History of Prior MI*	N	35	22.3	36	24.7	68	23.9	139	23.7
	Y	1	0.6	3	2.1	6	2.1	10	1.7
	U	121	77.1	107	73.3	210	73.9	438	74.6
If Left Vent. Ejection Fraction <50%*	Segmental Abnormalities	3	1.9	2	1.4	1	0.4	6	1.0
	Global Abnormalities	6	3.8	4	2.7	3	1.1	13	2.2
	Segmental and Global Abnormalities	2	1.3	1	0.7	2	0.7	5	0.9
	No Abnormalities	1	0.6	1	0.7	9	3.2	11	1.9
	Not Reported	145	92.4	138	94.5	269	94.7	552	94.0
Coronary Angiogram Result*	Abnormal	.	.	2	1.4	2	0.7	4	0.7
	Normal	.	.	.	.	2	0.7	2	0.3
	Angiogram Not Done	29	18.5	33	22.6	56	19.7	118	20.1
	Not Reported	128	81.5	111	76.0	224	78.9	463	78.9
Right Heart Catheterization*	N	32	20.4	38	26.0	73	25.7	143	24.4
	Y	4	2.5	1	0.7	2	0.7	7	1.2
	U	121	77.1	107	73.3	209	73.6	437	74.4
Myocardial Biopsy*	N	30	19.1	34	23.3	59	20.8	123	21.0
	U	127	80.9	112	76.7	225	79.2	464	79.0

* Currently, data submission for these items is not mandatory when the heart was not recovered. These fields will be required for all deceased donors in May 2004.

Table 6B. Continuous donor characteristics for potentially suitable donors with no heart match run

	18-35 (N = 157)					36-45 (N = 146)					46-55 (N = 284)				
	# with Data	Mean	Std Error	10th %ile	90th %ile	# with Data	Mean	Std Error	10th %ile	90th %ile	# with Data	Mean	Std Error	10th %ile	90th %ile
BMI (kg/m²)	157	25.8	0.5	19.9	33.1	146	27.7	0.5	20.8	36.3	284	27.1	0.3	20.9	35.2
Terminal Serum Creatinine	157	1.6	0.1	0.6	3.0	143	1.6	0.2	0.6	2.6	283	1.7	0.1	0.7	3.1
Terminal BUN	157	17.3	1.1	7.0	33.0	143	19.0	1.1	7.0	35.0	282	21.3	1.1	7.0	37.0
Terminal Total Bilirubin	154	1.1	0.1	0.3	1.9	134	1.3	0.2	0.3	2.0	266	0.9	0.1	0.2	1.6
Terminal SGOT/AST	154	205.8	49.2	25.0	276.0	134	178.3	72.8	19.0	210.0	268	120.3	14.8	18.0	248.0
Terminal SGPT/ALT	154	159.9	43.4	16.0	312.0	135	124.5	31.5	18.0	190.0	269	91.0	13.1	13.0	150.0
PO_2 on 100% O_2**	24	378.2	34.6	75.0	523.0	17	359.8	38.2	82.0	529.0	27	325.4	28.8	83.5	488.2
LV Ejection Fraction*	15	33.3	3.7	15.0	51.0	13	42.4	3.9	25.0	55.0	21	40.3	3.8	19.0	65.0
CVP*	2	8.0	0.0	8.0	8.0	0	.	.	.	.	3	7.3	2.8	4.0	13.0
PA Diastolic*	3	30.7	4.3	22.0	35.0	1	4.0	.	4.0	4.0	2	18.5	8.5	10.0	27.0
PA Systolic*	3	50.7	24.8	21.0	100.0	1	10.0	.	10.0	10.0	2	27.5	8.5	19.0	36.0
PCW*	3	9.7	1.5	7.0	12.0	1	12.0	.	12.0	12.0	2	15.0	2.0	13.0	17.0
Cardiac Output*	3	7.2	2.7	4.0	12.5	0	.	.	.	.	2	7.0	0.9	6.1	7.9

* Currently, data submission for these items is not mandatory when the heart was not recovered. These fields will be required for all deceased donors in May 2004.

** Data submission not required when neither lung was recovered.

REVIEWED AT APRIL 16, 2004, TELECONFERENCE

OPTN/UNOS Thoracic Committee
Descriptive Data Request

Lung Consent and Recovery Information for Potentially Suitable Donors

Prepared for:
Thoracic Committee meeting
January 23, 2004

By:
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Committee Request

Examine the lung transplant rate by OPO for donors from whom consent for lung recovery was obtained, limited to brain-dead donors between 18 and 55 years who were not positive for any serological tests (excluding CMV+). Tabulate the percentage of lung transplants that were performed locally. Tabulate the number of offers made and the rank order of the acceptor for transplanted lungs.

After further discussion at the Heart Recovery and Use Subcommittee, the following additional requests were made regarding donors from whom neither lung was transplanted: provide detailed medical and social History information, tabulate the other organs for which matches were run, and tabulate the other organs that were transplanted. The medical History items of particular interest were pO2, smoking history, cause of death and use of hormonal resuscitation.

Background/Purpose

Improving lung recovery rates has been a topic of much discussion within the Thoracic Committee. In an effort to identify potential areas of improvement, the Committee suggested that analysis should be limited to those donors that truly have potential to be lung donors, rather than examining all donors.

After the Subcommittee reviewed the original tables, additional concerns were raised regarding the donors for whom no match was run, after limiting the criteria to the most reasonable pool of potentially suitable heart donors. One concern raised during the discussion of the Subcommittee is that detailed cardiac information is not available on these donors and there may be legitimate reasons why the heart was not transplanted. By examining medical and social History characteristics, some possible contraindications to transplant could be reviewed, though there may be others that are not currently collected.

Data and Conventions

All deceased brain-dead donors between the ages of 18 and 55, who were not serologically positive (excluding CMV+) and were recovered between January 1, 2002, and June 30, 2003, were included in the analysis cohort for all tabulations.

As there are several OPOs involved in sharing arrangements for thoracic allocation (i.e., either several OPOs have a single combined local list or there is an interim allocation to other OPOs in the state after allocation to the recovering OPO but prior to allocation to Zone A), many of the tabulations make a distinction between local (OPO only) and sharing agreement (other OPOs in the state but prior to Zone A).

Summary of Results

Figure 1.

- There were 4786 donors recovered between January 1, 2002, and June 30, 2003, meeting the suitability criteria for whom consent for lung donation was obtained.
- Of these donors, at least one lung was transplanted in 1015 (21%). From these donors 1219 lung transplants were performed involving 1810 lungs.
- Of the 3771 donors in whom the lung was not transplanted, there was approximately an equal distribution between the following four group: the lung match was not run; a match was run but offer efforts were not reported; only local offers were made (include those to OPOs in a sharing arrangement) and offers were made in Zone A or beyond.

Table 1A/Figure 2A. Transplant rates within region

- The percentage of potentially suitable donors with at least 1 lung transplanted ranged across region from 14% to 25% (US rate = 21%).
- Of the lungs transplanted, there was a fairly broad range of the percentage that were transplanted outside the local OPO or sharing agreement of recovery. The percentage of Zone A or beyond transplanted organs for all OPOs within a region ranged from 17% to 53%.

Table 1B/Figure 2B. Transplant rates by OPO

- The percentage of potentially suitable donors with at least 1 lung transplanted ranged across OPO from 0% to 38% (US rate = 21%).
- Of the lungs transplanted, the range of Zone A or beyond transplanted organs by OPO ranged from 0% to 100%.

Table 2. Number of offers made for patients and to centers

- The number of potential recipients and centers for whom offers were made (Table 2) differ substantially by whether the lung was transplanted and the geographic difference of the transplant/furthest offer.

- Transplanted lungs
  - There were 1167 transplanted lungs with complete match runs available for analysis. (En-bloc/double lungs offered simultaneously are counted as 1 lung for this table.)
  - Offers to potential recipients
    - On average, the lung was accepted for the 30th potential recipient.
    - The acceptor ranged from the 1st position on the match run to the 933rd position.
    - At least half of the acceptors were within the first 8 positions on the match run.
  - Offers to centers
    - On average, offers were made to approximately 4 centers.
    - At most 45 centers were contacted for the lung to be accepted.
    - In at least half of the matches the lung was accepted by the first or second center.

- Non-transplanted lungs
  - There were 1293 non-transplanted lungs with complete match runs available for analysis.
  - Offers to potential recipients
    - On average, placement efforts were stopped after offers to the 40th potential recipient.
    - The last potential recipient to whom offers were made ranged from the 1st position on the match run to the 875th on the match run.
    - In half of the matches placement efforts were discontinued prior to or at the 19th potential recipient on the match run.
  - Offers to centers
    - On average, placement efforts were discontinued after offers were made to 4 centers.
    - At most 54 centers were contacted before placement efforts ended.
    - In at least half of the match runs, offers were made to only 3 centers.

Table 3. Refusal reasons

- The distribution of refusal reasons differs considerably by whether the organ was transplanted and the geographic distance of the offers.
- For lungs that weren't transplanted for which only local or Zone A offers were made, approximately 60% were turned down for donor quality or donor size/weight.
- Transplanted lungs had a much higher percentage of refusals for donor size/weight than the non-transplanted organs, with almost half of refusals for locally transplanted organs due to donor size/weight.

Table 4. Match runs for other organs

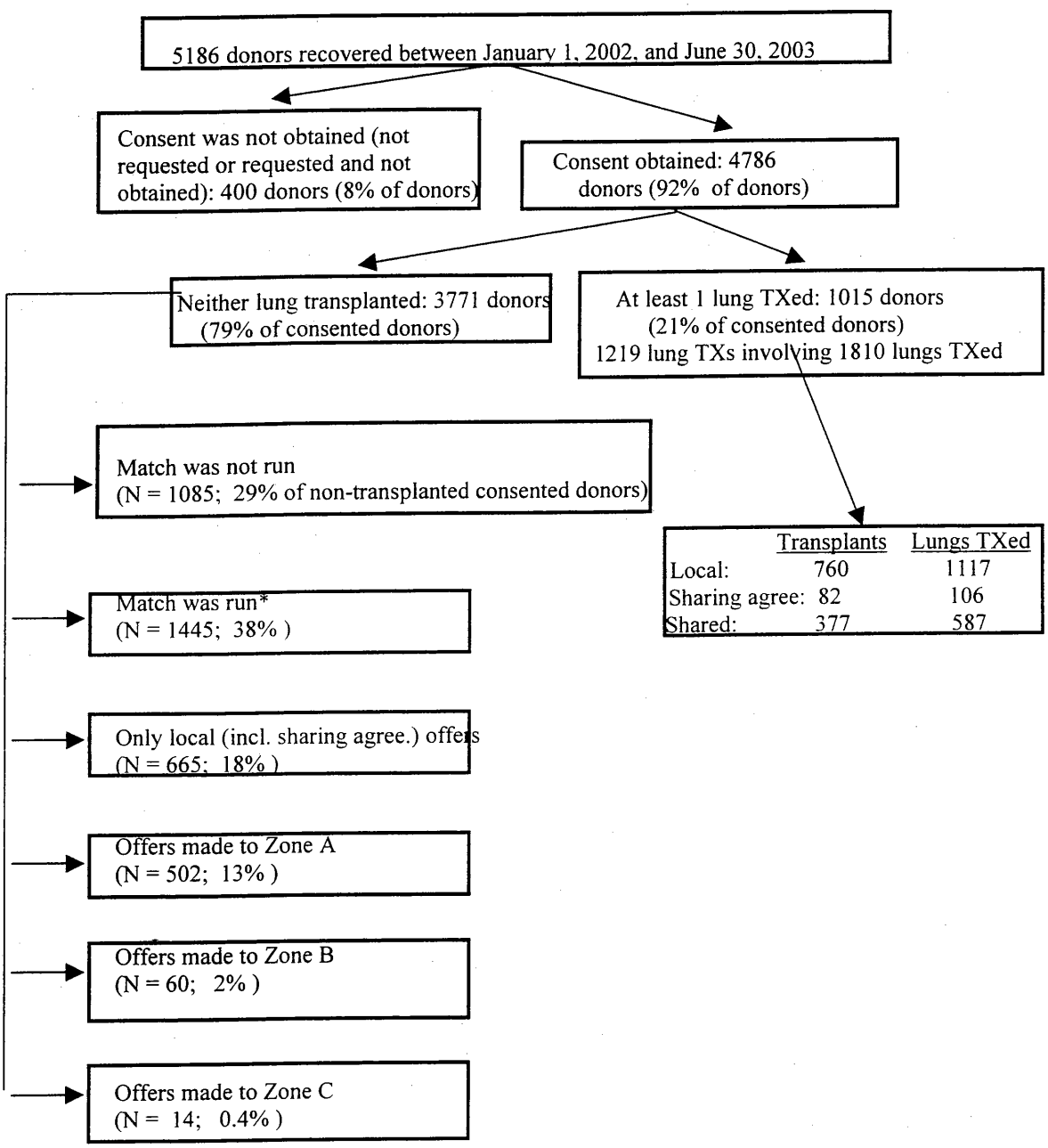
- All donors had at least one match run.
- The vast majority of donors had a match run for kidney and for liver.
- If a lung match was run, at least 92% of the donors had a heart match run also. But for the group of donors with no lung match, only 61% had a heart match.

Table 5. Other organs transplanted

- For each match type, 1-3% of donors had no organs transplanted, with the highest rate for donors having no lung match run.
- The heart was transplanted in between 29-53% of these donors.
- The liver and at least one kidney were transplanted in approximately 80-90% of the donors. The lower rates were seen in those donors that did not have a lung match run.

Results

Figure 1. Utilization of lungs for donors recovered between January 1, 2002, and June 30, 2003 for brain-dead donors aged 18-55, no positive serology (Hepatitis B, Hepatitis C, HIV, HTLV or VDRL)



* Match was run but not possible to determine if offers were made or not.

Table 1A. Lung recovery information by region for deceased potentially suitable donors Recovered between January 1, 2002, and June 30, 2003*

Region	Number of donors with lung consent	Consented, neither lung transplanted		At least 1 lung transplanted		Lungs TXed	Lungs transplanted locally		Lungs transplanted within sharing agreement		Lungs shared and transplanted	
		N	% of donors	N	% of donors		N	% of Txed lungs	N	% of Txed lungs	N	% of Txed lungs
US	4786	3771	78.8%	1015	21.2%	1810	1117	61.7%	106	5.86%	587	32.4%
1	185	143	77.3%	42	22.7%	74	49	66.2%	0	0.0%	25	33.8%
2	506	397	78.5%	109	21.5%	205	140	68.3%	0	0.0%	65	31.7%
3	762	608	79.8%	154	20.2%	267	132	49.4%	40	15.0%	95	35.6%
4	492	386	78.5%	106	21.5%	186	144	77.4%	0	0.0%	42	22.6%
5	709	550	77.6%	159	22.4%	277	173	62.5%	0	0.0%	104	37.5%
6	190	154	81.1%	36	18.9%	68	32	47.1%	0	0.0%	36	52.9%
7	468	363	77.6%	105	22.4%	188	139	73.9%	0	0.0%	49	26.1%
8	311	240	77.2%	71	22.8%	132	67	50.8%	0	0.0%	65	49.2%
9	217	186	85.7%	31	14.3%	57	27	47.4%	9	15.8%	21	36.8%
10	478	360	75.3%	118	24.7%	206	118	57.3%	52	25.2%	36	17.5%
11	468	384	82.1%	84	17.9%	150	96	64.0%	5	3.33%	49	32.7%

**Potentially suitable: brain-dead donors aged 18-55, no positive serology*

Range of % not transplanted for regions: [61.7%, 100%]; median across regions: 79.8%
Range of % non-local/non-sharing agreement transplanted lungs for regions: [17.5%, 52.9%]; median across regions: 33.8%

Figure 2A. Lung recovery information by region for deceased potentially suitable donors*

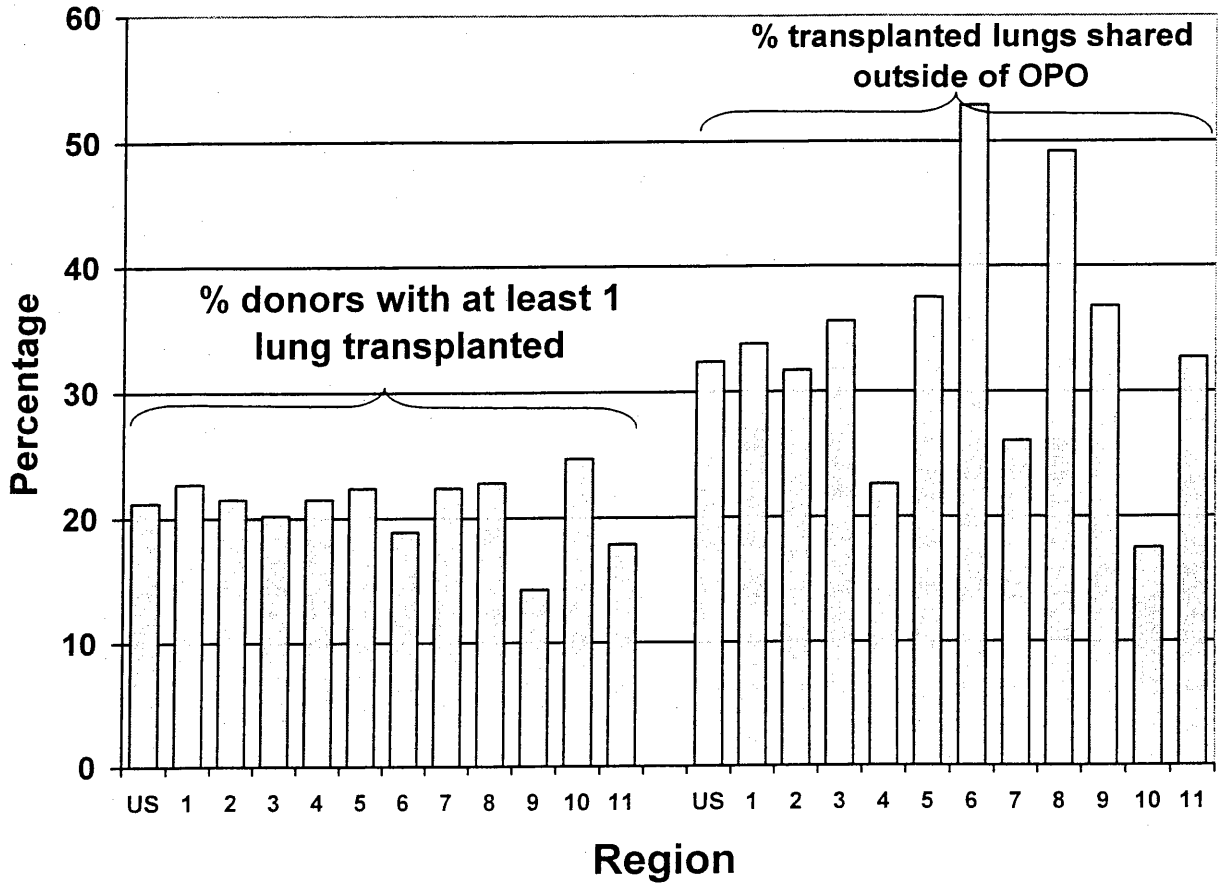


Table 1B. Lung recovery information by OPO for deceased potentially suitable* donors Recovered between January 1, 2002, and June 30, 2003

Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Lungs TXed	Lungs transplanted locally		Lungs transplanted in sharing agreement		Lungs shared and transplanted	
		N	%	N	N		N	%	N	%	N	%
US	*4786*	*3771*	*78.8%*	*1015*	*21.2%*	*1810*	*1117*	*61.7%*	*106*	*5.86%*	*587*	*32.4%*
1003	111	92	82.9%	19	17.1%	37	33	89.2%	0	0.0%	4	10.8%
1013	27	24	88.9%	3	11.1%	5	0	0.0%	0	0.0%	5	100%
1027	40	37	92.5%	3	7.50%	5	0	0.0%	0	0.0%	5	100%
1056	81	58	71.6%	23	28.4%	37	37	100%	0	0.0%	0	0.0%
1062	24	22	91.7%	2	8.33%	3	0	0.0%	3	100%	0	0.0%
1084	200	155	77.5%	45	22.5%	83	63	75.9%	0	0.0%	20	24.1%
1091	84	58	69.0%	26	31.0%	51	33	64.7%	0	0.0%	18	35.3%
1092	109	92	84.4%	17	15.6%	27	14	51.9%	3	11.1%	10	37.0%
1093	44	38	86.4%	6	13.6%	11	0	0.0%	0	0.0%	11	100%
1124	50	38	76.0%	12	24.0%	21	0	0.0%	20	95.2%	1	4.76%
1133	45	41	91.1%	4	8.89%	7	7	100%	0	0.0%	0	0.0%
1175	129	96	74.4%	33	25.6%	59	50	84.7%	0	0.0%	9	15.3%
1176	73	57	78.1%	16	21.9%	26	26	100%	0	0.0%	0	0.0%
1204	67	54	80.6%	13	19.4%	26	0	0.0%	0	0.0%	26	100%
1240	26	22	84.6%	4	15.4%	7	0	0.0%	0	0.0%	7	100%
1254	59	44	74.6%	15	25.4%	29	0	0.0%	0	0.0%	29	100%
1274	155	127	81.9%	28	18.1%	51	47	92.2%	0	0.0%	4	7.84%
1285	37	26	70.3%	11	29.7%	21	0	0.0%	0	0.0%	21	100%
1305	34	25	73.5%	9	26.5%	17	0	0.0%	16	94.1%	1	5.88%
1309	31	29	93.5%	2	6.45%	4	0	0.0%	0	0.0%	4	100%
1359	38	29	76.3%	9	23.7%	18	0	0.0%	0	0.0%	18	100%
1369	62	44	71.0%	18	29.0%	29	24	82.8%	2	6.90%	3	10.3%
1377	256	205	80.1%	51	19.9%	88	76	86.4%	0	0.0%	12	13.6%
1380	67	47	70.1%	20	29.9%	40	30	75.0%	0	0.0%	10	25.0%
1388	47	36	76.6%	11	23.4%	18	2	11.1%	0	0.0%	16	88.9%
1391	78	53	67.9%	25	32.1%	44	41	93.2%	0	0.0%	3	6.82%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [61.7%, 100.0%]; median across OPOs: 80.6%
Range of % non-local/non-sharing agreement transplanted lungs for OPOs: [0%, 100%]; median across OPOs: 24.8%

Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Lungs TXed	Lungs transplanted locally		Lungs transplanted in sharing agreement		Lungs shared and transplanted	
		N	%	N	N		N	%	N	%	N	%
1393	59	48	81.4%	11	18.6%	17	0	0.0%	13	76.5%	4	23.5%
1395	25	22	88.0%	3	12.0%	6	0	0.0%	4	66.7%	2	33.3%
1405	138	116	84.1%	22	15.9%	40	27	67.5%	0	0.0%	13	32.5%
1410	79	65	82.3%	14	17.7%	26	0	0.0%	0	0.0%	26	100%
1413	29	26	89.7%	3	10.3%	5	0	0.0%	2	40.0%	3	60.0%
1422	76	57	75.0%	19	25.0%	30	28	93.3%	0	0.0%	2	6.67%
1429	151	120	79.5%	31	20.5%	53	40	75.5%	0	0.0%	13	24.5%
1439	65	51	78.5%	14	21.5%	24	8	33.3%	15	62.5%	1	4.17%
1443	148	117	79.1%	31	20.9%	53	49	92.5%	0	0.0%	4	7.55%
1447	48	35	72.9%	13	27.1%	25	19	76.0%	0	0.0%	6	24.0%
1464	66	58	87.9%	8	12.1%	15	15	100%	0	0.0%	0	0.0%
1466	46	30	65.2%	16	34.8%	27	19	70.4%	1	3.70%	7	25.9%
1467	79	72	91.1%	7	8.86%	10	3	30.0%	7	70.0%	0	0.0%
1506	112	91	81.3%	21	18.8%	39	32	82.1%	0	0.0%	7	17.9%
1511	68	50	73.5%	18	26.5%	34	25	73.5%	0	0.0%	9	26.5%
1519	94	73	77.7%	21	22.3%	42	39	92.9%	0	0.0%	3	7.14%
1522	42	40	95.2%	2	4.76%	3	0	0.0%	0	0.0%	3	100%
1526	176	133	75.6%	43	24.4%	73	56	76.7%	0	0.0%	17	23.3%
1528	72	60	83.3%	12	16.7%	21	17	81.0%	0	0.0%	4	19.0%
1573	30	26	86.7%	4	13.3%	8	0	0.0%	2	25.0%	6	75.0%
1585	12	10	83.3%	2	16.7%	4	0	0.0%	0	0.0%	4	100%
1593	132	96	72.7%	36	27.3%	64	51	79.7%	0	0.0%	13	20.3%
1607	97	71	73.2%	26	26.8%	45	28	62.2%	0	0.0%	17	37.8%
1632	52	48	92.3%	4	7.69%	7	5	71.4%	0	0.0%	2	28.6%
1644	19	19	100%	0	0.0%	0	0	.	0	.	0	.
1655	64	55	85.9%	9	14.1%	17	13	76.5%	0	0.0%	4	23.5%
1662	50	40	80.0%	10	20.0%	18	8	44.4%	0	0.0%	10	55.6%
1665	149	123	82.6%	26	17.4%	45	14	31.1%	0	0.0%	31	68.9%
1681	94	77	81.9%	17	18.1%	33	0	0.0%	0	0.0%	33	100%
1710	216	170	78.7%	46	21.3%	85	55	64.7%	0	0.0%	30	35.3%
1720	98	79	80.6%	19	19.4%	35	15	42.9%	14	40.0%	6	17.1%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

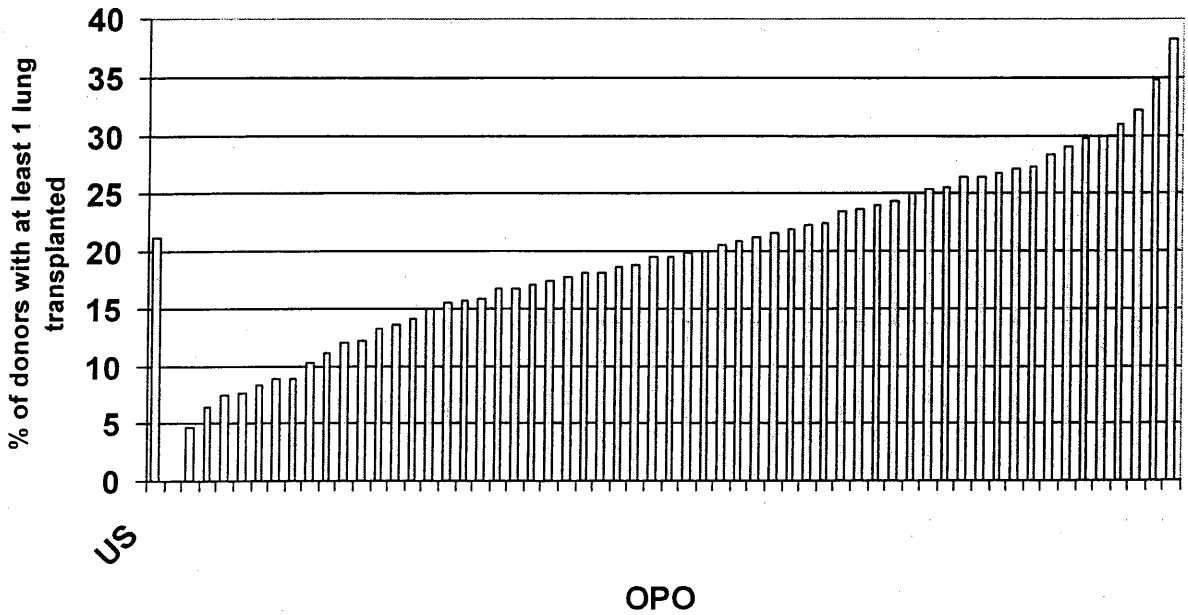
Range of % not transplanted for OPOs: [61.7%, 100.0%]; median across OPOs: 80.6%
Range of % non-local/non-sharing agreement transplanted lungs for OPOs: [0%, 100%]; median across OPOs: 24.8%

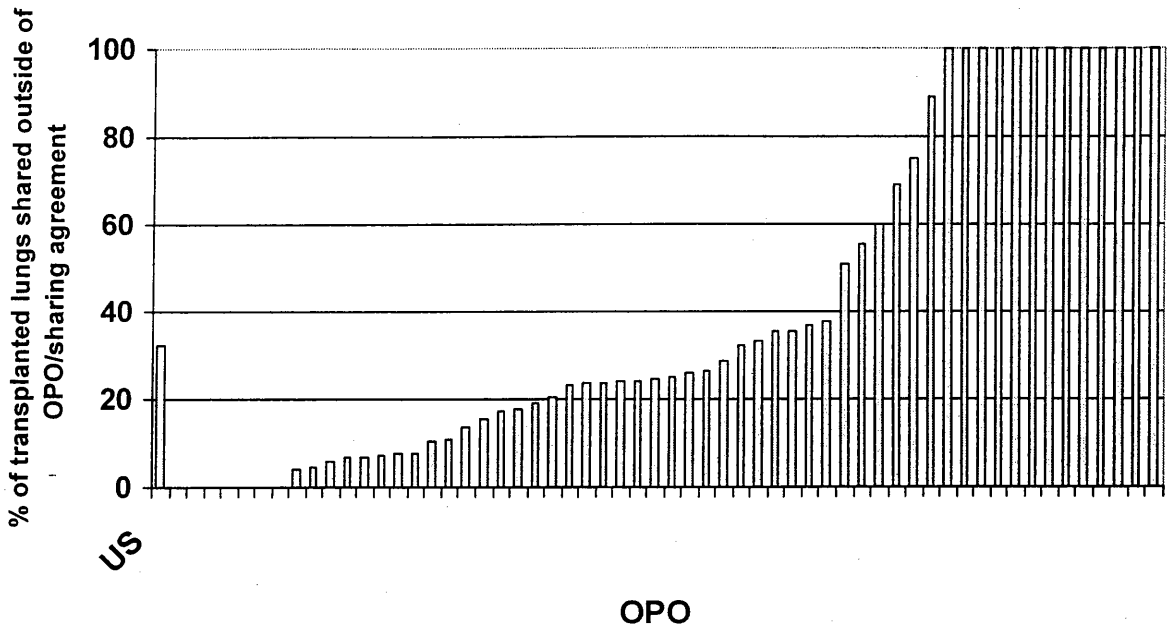
Encrypted OPO	Number of consented donors	Consented, not transplanted		Transplanted		Lungs TXed	Lungs transplanted locally		Lungs transplanted in sharing agreement		Lungs shared and transplanted	
		N	%	N	N		N	%	N	%	N	%
1725	206	127	61.7%	79	38.3%	138	68	49.3%	0	0.0%	70	50.7%
1756	20	17	85.0%	3	15.0%	4	0	0.0%	4	100%	0	0.0%

*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [61.7%, 100.0%]; median across OPOs: 80.6%
Range of % non-local/non-sharing agreement transplanted lungs for OPOs: [0%, 100%]; median across OPOs: 24.8%

Figure 2B. Lung recovery information by OPO for deceased potentially suitable donors*





*Potentially suitable: brain-dead donors ages 18-55, no positive serology

Range of % not transplanted for OPOs: [61.7%, 100.0%]; median across OPOs: 80.6%
Range of % non-local/non-sharing agreement transplanted lungs for OPOs: [0%, 100%]; median across OPOs: 24.8%

Table 2. Number of offers made on each lung for which a match was run
Offers tabulate separately for potential recipients and for centers

Donor group	Offer/acceptance type	Number of lungs offered*	Offers for potential recipients				Offers to centers			
			Mean	Std. Dev.	Range	Median	Mean	Std. Dev.	Range	Median
Transplanted	Transplanted - Local	746	10.8	21.2	[1, 338]	4	1.6	1.4	[1, 30]	1
	Transplanted – Within sharing agreement	77	13.4	13.9	[1, 74]	7	2.0	0.7	[1, 4]	2
	Transplanted – Shared (outside OPO and outside sharing agreement)	344	75.4	129.5	[1, 933]	29	8.3	7.2	[1, 45]	6
	ALL	*1167*	*30.0*	*78.1*	*[1, 933]*	*8*	*3.6*	*5.1*	*[1, 45]*	*2*
Not transplanted	Only Local offers made (may include offers within a sharing agreement)	680	25.9	37.3	[1, 210]	12	1.9	1.0	[1, 12]	2
	Zone A offers made	530	50.7	63.0	[1, 632]	27	6.2	3.6	[1, 32]	5
	Zone B offers made	65	68.3	72.6	[3, 318]	39	7.8	5.6	[1, 36]	7
	Zone C offers made	18	126.8	208.5	[1, 875]	52	14.8	11.4	[1, 54]	13
	ALL	*1293*	*39.6*	*59.0*	*[1, 875]*	*19*	*4.1*	*3.9*	*[1, 54]*	*3*

*NOTES:

- Double/en-bloc lungs offered from 1 match are counted as 1 lung offered in this table.
- The number of transplanted lungs offered is slightly lower than the number of lung transplants performed primarily due to match runs with incomplete offer/refusal information.
- The number of lungs not transplanted is higher than in Figure 1 as some donors had one lung transplanted and one lung offered but not transplanted. Organs in the latter group are included in the not transplanted category in this table.

Table 3. Refusal reasons for lung match runs

Percentage of offers by reason with reasons weighted by number of refusals per donor

Refusal reason	Not transplanted					Transplanted			
	TOTAL (N = 1284)	Only Local* offers made (N = 672)	Zone A offers made (N = 529)	Zone B offers made (N = 65)	Zone C offers made (N = 18)	TOTAL (N = 993)	TXed - Local (N = 589)	TXed - Sharing agreement (N = 67)	TXed – Shared (N = 337)
Donor Quality	47.4	51.1	46.0	27.5	21.0	8.7	4.9	11.4	14.7
Donor Size/Weight	12.9	10.0	15.4	21.4	17.1	41.9	49.4	31.3	30.8
Abnormal Blood Gases	8.9	12.8	4.9	3.3	.	0.8	0.4	.	1.7
Abnormal Chest X-Ray	3.5	4.0	2.4	5.1	10.7	0.7	0.7	.	0.8
Abnormal Bronchoscopy Results	3.4	3.8	3.0	3.4	2.2	0.9	0.9	.	1.1
Other: Other Specify	3.2	2.2	3.9	5.4	11.5	5.4	4.6	4.1	7.0
Multiple Organ Transplant Required	3.0	1.2	5.1	4.7	5.3	8.3	7.8	6.7	9.4
Lung test results unavail, not done, unacceptable	2.2	2.7	1.4	3.1	1.4	0.5	0.1	1.6	1.0
Donor Social History	1.9	1.2	2.9	0.7	.	0.6	0.3	1.2	1.1
Recipient Unavailable	1.8	1.1	2.5	3.7	2.1	4.9	5.2	1.8	5.0
Operational-transportation, logistics, distance	1.5	0.6	2.1	4.0	10.9	2.0	2.1	1.2	2.1
Surgeon Unavailable-currently performing	1.5	1.1	1.6	4.8	4.9	2.9	1.5	15.5	2.8
Recipient Transplanted/Inactive	1.5	1.3	1.1	5.0	6.6	4.3	5.2	0.3	3.6
Heavy workload-program unable to accept	1.4	1.4	1.4	1.6	1.5	1.5	0.9	7.3	1.3
Recipient testing results unavailable	1.0	0.2	2.1	0.9	1.0	1.8	0.8	1.9	3.6
Organ Anatomical Damage or Defect	1.0	1.7	0.2	0.1	0.2	0.1	0.2	.	0.1
Recipient Ill	0.8	0.7	0.9	2.3	0.5	4.2	5.6	5.2	1.5
Patient condition improved, transplant not needed	0.8	0.9	0.6	1.5	0.2	2.3	2.4	3.5	1.8
Positive Serological Tests	0.6	0.7	0.4	.	0.3	1.1	1.5	2.0	0.2
Positive Crossmatch	0.5	0.5	0.7	0.0	0.0	2.0	2.7	0.2	1.1
Donor Medical Urgency	0.3	0.1	0.5	0.8	.	2.2	0.3	.	5.9
Donor Age	0.3	0.2	0.4	0.2	.	0.1	0.1	0.7	0.0
Abnormal Echocardiogram	0.2	0.3	0.1	.	.	0.0	.	.	0.0
HLA mismatch unacceptable	0.1	0.1	0.1	0.0	.	0.5	0.3	1.1	0.8
Organ Preservation	0.1	.	0.1	0.1	2.6	0.0	.	.	0.1

Refusal reason	Not transplanted					Transplanted			
	TOTAL (N = 1284)	Only Local* offers made (N = 672)	Zone A offers made (N = 529)	Zone B offers made (N = 65)	Zone C offers made (N = 18)	TOTAL (N = 993)	TXed - Local (N = 589)	TXed - Sharing agreement (N = 67)	TXed – Shared (N = 337)
Elevated Creatinine	0.1	0.1	.	.	.	.	.	.	.
Other: Multi-organ Transplant	0.1	0.0	0.0	0.1	.	0.8	0.6	0.2	1.2
Bypassed; another patient medically urgent	0.0	0.1	0.0	.	.	1.2	0.9	2.7	1.3
Kidney test results unavailable, not done, unacceptable	0.0	.	0.1	.	.	.	.	.	.
Donor ABO	0.0	.	0.1	.	.	0.0	.	.	0.0
Recipient Refused	0.0	0.0	0.0	0.1	.	0.2	0.2	.	0.1
Liver: Abnormal Biopsy	0.0	0.0	.	.	.	.	.	.	.
Heart test results unavailable, not done, unacceptable	0.0	.	0.0	.	.	0.1	0.2	.	.
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

The refusal reasons of each potential recipient for each donor organ were weighted with weights corresponding to their relative frequency. Without weighting the reasons by their relative frequency, the refusals for one organ with 1000 offers would have the same influence as 50 organs with 20 refusals each. The weights for all refusal reasons total to 1 for each organ. For example, if all of the refusals for an organ were for abnormal echo then it would have a weight of 1. But if a third of the refusals for an organ were for abnormal echo and two-thirds were for donor quality then abnormal echo would have a weight of 0.33 and donor quality would have a weight of 0.67. These weights were then averaged over the organs in each group to obtain the percentages in the table. Missing values in the table indicate that there were no refusals for that particular reason. A percentage of 0.0 indicates that there was at least one potential recipient with that refusal reason.

*NOTES:

- The number of matches for which there are refusal reasons is lower than the number for which there are matches in Table 2 due to lungs accepted on the first offer. These are primarily transplanted organs though there were some non-transplanted lungs that were accepted for transplant on the first offer.
- Local offers for non-transplanted lungs include offers made within the sharing agreement.

Table 4. Other organs for which matches were run in donors with neither lung transplanted

Type	Matches run	Lung match not run		Match was run*		Only local offers		Zone A/B/C offers		All	
		N	%	N	%	N	%	N	%	N	%
Organ	Heart	664	61.2	1364	94.4	626	94.1	531	92.2	3185	84.5
	Intestine	168	15.5	529	36.6	313	47.1	229	39.8	1239	32.9
	Kidney	1003	92.4	1406	97.3	646	97.1	560	97.2	3615	95.9
	Liver	1050	96.8	1436	99.4	659	99.1	570	99.0	3715	98.5
	Pancreas	708	65.3	1249	86.4	594	89.3	516	89.6	3067	81.3
Organ combination	Heart	3	0.3	1	0.1	1	0.2	1	0.2	6	0.2
	Heart\Intestine	.	.	.	.	.	.	1	0.2	1	0.0
	Heart\Intestine\Kidney	.	.	.	.	1	0.2	.	.	1	0.0
	Heart\Intestine\Kidney-Pancreas\Liver\Pancreas	.	.	.	.	2	0.3	.	.	2	0.1
	Heart\Intestine\Kidney-Pancreas\Pancreas	.	.	1	0.1	.	.	.	.	1	0.0
	Heart\Intestine\Kidney\Kidney-Pancreas\Liver	1	0.1	7	0.5	.	.	.	.	8	0.2
	Heart\Intestine\Kidney\Kidney-Pancreas\Liver\Pancreas	108	10.0	429	29.7	251	37.7	173	30.0	961	25.5
	Heart\Intestine\Kidney\Kidney-Pancreas\Pancreas	1	0.1	1	0.1	2	0.3	.	.	4	0.1
	Heart\Intestine\Kidney\Liver	8	0.7	27	1.9	16	2.4	18	3.1	69	1.8
	Heart\Intestine\Kidney\Liver\Pancreas	12	1.1	37	2.6	23	3.5	20	3.5	92	2.4
	Heart\Intestine\Liver	1	0.1	6	0.4	5	0.8	2	0.3	14	0.4
	Heart\Intestine\Liver\Pancreas	3	0.3	6	0.4	2	0.3	2	0.3	13	0.3
	Heart\Kidney	3	0.3	1	0.1	.	.	1	0.2	5	0.1
	Heart\Kidney\Kidney-Pancreas	1	0.1	.	.	.	.	.	.	1	0.0
	Heart\Kidney\Kidney-Pancreas\Liver	18	1.7	21	1.5	8	1.2	6	1.0	53	1.4
	Heart\Kidney\Kidney-Pancreas\Liver\Pancreas	307	28.3	613	42.4	249	37.4	238	41.3	1407	37.3
	Heart\Kidney\Kidney-Pancreas\Pancreas	2	0.2	3	0.2	1	0.2	2	0.3	8	0.2
	Heart\Kidney\Liver	121	11.2	124	8.6	36	5.4	27	4.7	308	8.2
	Heart\Kidney\Liver\Pancreas	42	3.9	67	4.6	20	3.0	35	6.1	164	4.3
	Heart\Kidney\Pancreas	1	0.1	1	0.1	1	0.2	.	.	3	0.1
	Heart\Liver	26	2.4	14	1.0	4	0.6	3	0.5	47	1.2
	Heart\Liver\Pancreas	6	0.6	5	0.3	4	0.6	2	0.3	17	0.5
	Intestine\Kidney\Kidney-Pancreas\Liver\Pancreas	25	2.3	13	0.9	5	0.8	11	1.9	54	1.4
	Intestine\Kidney\Liver	6	0.6	.	.	1	0.2	1	0.2	8	0.2

Type	Matches run	Lung match not run		Match was run*		Only local offers		Zone A/B/C offers		All	
		N	%	N	%	N	%	N	%	N	%
	Intestine\Kidney\Liver\Pancreas	3	0.3	1	0.1	3	0.5	.	.	7	0.2
	Intestine\Liver	.	.	1	0.1	.	.	1	0.2	2	0.1
	Intestine\Liver\Pancreas	.	.	.	.	2	0.3	.	.	2	0.1
	Kidney	23	2.1	1	0.1	.	.	.	.	24	0.6
	Kidney-Pancreas\Liver\Pancreas	.	.	1	0.1	.	.	.	.	1	0.0
	Kidney\Kidney-Pancreas\Liver	6	0.6	2	0.1	1	0.2	.	.	9	0.2
	Kidney\Kidney-Pancreas\Liver\Pancreas	142	13.1	37	2.6	19	2.9	24	4.2	222	5.9
	Kidney\Kidney-Pancreas\Pancreas	1	0.1	.	.	.	.	1	0.2	2	0.1
	Kidney\Liver	151	13.9	15	1.0	6	0.9	2	0.3	174	4.6
	Kidney\Liver\Pancreas	21	1.9	4	0.3	1	0.2	1	0.2	27	0.7
	Liver	35	3.2	6	0.4	1	0.2	3	0.5	45	1.2
	Liver\Pancreas	8	0.7	.	.	.	.	1	0.2	9	0.2

Table 5. Other organs that were transplanted from donors with neither lung transplanted

Type	Organ type transplanted	Lung match not run		Match was run*		Only local offers		Zone A/B/C offers		All	
		N	%	N	%	N	N	%	N	%	N
Organ	Heart	312	28.8	615	42.6	324	48.7	305	53.0	1556	41.3
	Intestine	5	0.5	12	0.8	6	0.9	5	0.9	28	0.7
	Kidney	907	83.6	1305	90.3	599	90.1	528	91.7	3339	88.5
	Liver	854	78.7	1241	85.9	577	86.8	503	87.3	3175	84.2
	Pancreas	183	16.9	440	30.4	215	32.3	202	35.1	1040	27.6
Organ combination	Heart	14	1.3	13	0.9	4	0.6	7	1.2	38	1.0
	Kidney	142	13.1	107	7.4	35	5.3	33	5.7	317	8.4
	Kidney/Heart	36	3.3	50	3.5	30	4.5	19	3.3	135	3.6
	Kidney/Intestine	1	0.1	.	.	.	.	.	.	1	0.0
	Kidney/Liver	383	35.3	437	30.2	171	25.7	150	26.0	1141	30.3
	Kidney/Liver/Heart	161	14.8	273	18.9	147	22.1	129	22.4	710	18.8
	Kidney/Liver/Intestine	3	0.3	2	0.1	2	0.3	.	.	7	0.2
	Kidney/Liver/Intestine/Heart	.	.	1	0.1	1	0.2	.	.	2	0.1
	Kidney/Liver/Pancreas	92	8.5	180	12.5	77	11.6	55	9.5	404	10.7
	Kidney/Liver/Pancreas/Heart	82	7.6	234	16.2	125	18.8	132	22.9	573	15.2
	Kidney/Liver/Pancreas/Intestine	1	0.1	1	0.1	.	.	1	0.2	3	0.1
	Kidney/Liver/Pancreas/Intestine/Heart	.	.	8	0.6	2	0.3	4	0.7	14	0.4
	Kidney/Pancreas	4	0.4	2	0.1	5	0.8	.	.	11	0.3
	Kidney/Pancreas/Heart	2	0.2	10	0.7	4	0.6	5	0.9	21	0.6
	Liver	114	10.5	75	5.2	40	6.0	21	3.6	250	6.6
	Liver /Heart	16	1.5	25	1.7	9	1.4	7	1.2	57	1.5
	Liver /Intestine/Heart	.	.	.	.	1	0.2	.	.	1	0.0
	Liver /Pancreas	1	0.1	4	0.3	1	0.2	3	0.5	9	0.2
	Liver /Pancreas/Heart	1	0.1	1	0.1	1	0.2	1	0.2	4	0.1
	Pancreas /Heart	.	.	.	.	.	.	1	0.2	1	0.0
	NO ORGAN TRANSPLANTED	32	2.9	22	1.5	10	1.5	8	1.4	72	1.9

NOTE: The organ combinations are those transplanted from a donor, not necessarily the organ combinations that an individual recipient received.

Table 6. Donor characteristics for donors with neither lung transplanted

		Match/offer type								All	
		Match was not run		Match was run*		Only Local offers		Zone A/B/C offers			
		N	%	N	%	N	%	N	%	N	%
Cause of death	**Anoxia**	181	16.7	133	9.2	63	9.5	64	11.1	441	11.7
	Cerebrovascular/Stroke	447	41.2	567	39.2	270	40.6	227	39.4	1511	40.1
	Head Trauma	423	39.0	720	49.8	314	47.2	269	46.7	1726	45.8
	CNS Tumor	14	1.3	9	0.6	12	1.8	8	1.4	43	1.1
	Other Specify	20	1.8	16	1.1	6	0.9	8	1.4	50	1.3
Hormonal resuscitation (steroids + T3/T4 + DDAVP)	**N**	856	78.9	1078	74.6	515	77.4	437	75.9	2886	76.5
	Y	135	12.4	190	13.1	101	15.2	93	16.1	519	13.8
	U	94	8.7	177	12.2	49	7.4	46	8.0	366	9.7
Prerecovery Steroids	**N**	233	21.5	361	25.0	147	22.1	148	25.7	889	23.6
	Y	761	70.1	909	62.9	471	70.8	384	66.7	2525	67.0
	U	91	8.4	175	12.1	47	7.1	44	7.6	357	9.5
Prerecovery Triiodothyronine-T3	**N**	963	88.8	1227	84.9	596	89.6	512	88.9	3298	87.5
	Y	29	2.7	42	2.9	25	3.8	20	3.5	116	3.1
	U	93	8.6	176	12.2	44	6.6	44	7.6	357	9.5
Prerecovery Thyroxine-T4	**N**	709	65.3	788	54.5	371	55.8	340	59.0	2208	58.6
	Y	283	26.1	480	33.2	249	37.4	192	33.3	1204	31.9
	U	93	8.6	177	12.2	45	6.8	44	7.6	359	9.5
Donor Given Synthetic Anti Diuretic Hormone (DDAVP)	**N**	603	55.6	736	50.9	324	48.7	246	42.7	1909	50.6
	Y	481	44.3	709	49.1	340	51.1	328	56.9	1858	49.3
	U	1	0.1	.	.	1	0.2	2	0.3	4	0.1
≥3 Inotropic Agents At Time Of Incision (Y/N)	**N**	1034	95.3	1367	94.6	647	97.3	561	97.4	3609	95.7
	Y	51	4.7	75	5.2	18	2.7	15	2.6	159	4.2
	U	.	.	3	0.2	.	.	.	.	3	0.1
Clinical infection	**None**	750	69.1	1013	70.1	428	64.4	352	61.1	2543	67.4
	Blood	17	1.6	26	1.8	5	0.8	11	1.9	59	1.6
	Blood /Other	4	0.4	3	0.2	1	0.2	1	0.2	9	0.2
	Blood /Pulmonary	11	1.0	11	0.8	8	1.2	5	0.9	35	0.9
	Blood /Pulmonary/Other	.	.	1	0.1	1	0.2	.	.	2	0.1
	Blood /Pulmonary/Urine	28	2.6	28	1.9	35	5.3	37	6.4	128	3.4
	Blood /Pulmonary/Urine/Other	2	0.2	2	0.1	1	0.2	1	0.2	6	0.2

		Match/offer type								All	
		Match was not run		Match was run*		Only Local offers		Zone A/B/C offers			
		N	%	N	%	N	%	N	%	N	%
Clinical infection (cont'd)	Blood /Urine	7	0.6	5	0.3	1	0.2	.	.	13	0.3
	Blood /Urine/Other	3	0.3	.	.	.	.	.	.	3	0.1
	Other	18	1.7	23	1.6	10	1.5	20	3.5	71	1.9
	Pulmonary	114	10.5	155	10.7	86	12.9	84	14.6	439	11.6
	Pulmonary /Other	2	0.2	3	0.2	2	0.3	.	.	7	0.2
	Pulmonary /Urine	5	0.5	15	1.0	11	1.7	7	1.2	38	1.0
	Pulmonary /Urine/Other	1	0.1	1	0.1	.	.	1	0.2	3	0.1
	Urine	19	1.8	23	1.6	7	1.1	8	1.4	57	1.5
	Urine /Other	2	0.2	3	0.2	.	.	.	.	5	0.1
	Unknown	102	9.4	133	9.2	69	10.4	49	8.5	353	9.4
Cigarette usage	History and current use	421	38.8	498	34.5	219	32.9	195	33.9	1333	35.3
	History but not current use	61	5.6	75	5.2	38	5.7	32	5.6	206	5.5
	History, current use unknown	14	1.3	14	1.0	18	2.7	15	2.6	61	1.6
	None	583	53.7	847	58.6	384	57.7	331	57.5	2145	56.9
	Usage unknown	6	0.6	11	0.8	6	0.9	3	0.5	26	0.7
Alcohol usage	History and current use	205	18.9	248	17.2	101	15.2	99	17.2	653	17.3
	History but not current use	51	4.7	62	4.3	49	7.4	32	5.6	194	5.1
	History, current use unknown	6	0.6	11	0.8	8	1.2	13	2.3	38	1.0
	None	818	75.4	1113	77.0	498	74.9	420	72.9	2849	75.6
	Usage unknown	5	0.5	11	0.8	9	1.4	12	2.1	37	1.0
IV drug usage	History and current use	10	0.9	11	0.8	4	0.6	6	1.0	31	0.8
	History but not current use	8	0.7	16	1.1	5	0.8	7	1.2	36	1.0
	History, current use unknown	3	0.3	2	0.1	4	0.6	2	0.3	11	0.3
	None	1049	96.7	1399	96.8	642	96.5	557	96.7	3647	96.7
	Usage unknown	15	1.4	17	1.2	10	1.5	4	0.7	46	1.2
Cocaine usage	History and current use	76	7.0	90	6.2	43	6.5	45	7.8	254	6.7
	History but not current use	50	4.6	68	4.7	35	5.3	36	6.3	189	5.0
	History, current use unknown	23	2.1	33	2.3	16	2.4	11	1.9	83	2.2
	None	914	84.2	1229	85.1	551	82.9	476	82.6	3170	84.1
	Usage unknown	22	2.0	25	1.7	20	3.0	8	1.4	75	2.0
Other drug usage	History and current use	200	18.4	250	17.3	97	14.6	107	18.6	654	17.3
	History but not current use	88	8.1	127	8.8	60	9.0	65	11.3	340	9.0

		Match/offer type								All	
		Match was not run		Match was run*		Only Local offers		Zone A/B/C offers			
		N	%	N	%	N	%	N	%	N	%
Other drug usage (cont'd)	History, current use unknown	23	2.1	35	2.4	19	2.9	19	3.3	96	2.5
	None	761	70.1	1013	70.1	472	71.0	379	65.8	2625	69.6
	Usage unknown	13	1.2	20	1.4	17	2.6	6	1.0	56	1.5
INSULIN DEPENDENT	No diabetes or diabetes status unknown	1011	93.2	1378	95.4	630	94.7	551	95.7	3570	94.7
	No	38	3.5	38	2.6	16	2.4	10	1.7	102	2.7
	Insulin Dependent Diabetes	12	1.1	7	0.5	6	0.9	3	0.5	28	0.7
	Non-Insulin Dependent Diabetes	3	0.3	5	0.3	3	0.5	3	0.5	14	0.4
	Diabetes, Dependency Unknown	14	1.3	14	1.0	9	1.4	7	1.2	44	1.2
	Unknown	7	0.6	3	0.2	1	0.2	2	0.3	13	0.3
History of Hypertension	N	788	72.6	1147	79.4	528	79.4	451	78.3	2914	77.3
	Y	286	26.4	289	20.0	129	19.4	121	21.0	825	21.9
	U	11	1.0	9	0.6	8	1.2	4	0.7	32	0.8
Lifestyle factors	No lifestyle factors	739	68.1	993	68.7	419	63.0	376	65.3	2527	67.0
	Prison	67	6.2	71	4.9	39	5.9	30	5.2	207	5.5
	Prison /Other	4	0.4	2	0.1	3	0.5	4	0.7	13	0.3
	Prison /Sexual Promiscuity	5	0.5	2	0.1	4	0.6	2	0.3	13	0.3
	Prison /Sexual Promiscuity/Other	1	0.1	.	.	.	.	.	.	1	0.0
	Prison /Tattoos	47	4.3	55	3.8	25	3.8	26	4.5	153	4.1
	Prison /Tattoos/Other	2	0.2	2	0.1	2	0.3	.	.	6	0.2
	Prison /Tattoos/Sexual Promiscuity	4	0.4	8	0.6	2	0.3	3	0.5	17	0.5
	Prison /Tattoos/Sexual Promiscuity/Other	1	0.1	.	.	.	.	1	0.2	2	0.1
	Sexual Promiscuity	6	0.6	10	0.7	3	0.5	6	1.0	25	0.7
	Sexual Promiscuity /Other	.	.	.	.	.	.	1	0.2	1	0.0
	Tattoos	130	12.0	207	14.3	101	15.2	63	10.9	501	13.3
	Tattoos /Other	12	1.1	11	0.8	5	0.8	8	1.4	36	1.0
	Tattoos /Sexual Promiscuity	3	0.3	9	0.6	5	0.8	6	1.0	23	0.6
	Tattoos /Sexual Promiscuity/Other	1	0.1	.	.	.	.	1	0.2	2	0.1
	Other	14	1.3	13	0.9	8	1.2	14	2.4	49	1.3
	Unknown	49	4.5	62	4.3	49	7.4	35	6.1	195	5.2

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		Match/offer type								All	
		Match was not run		Match was run*		Only Local offers		Zone A/B/C offers			
		N	%	N	%	N	%	N	%	N	%
Left Lung Bronchoscopic Abnormalities and Purulent Drainage*	**Bronchoscopy not done**	15	1.4	34	2.4	7	1.1	5	0.9	61	1.6
	Bronchoscopy normal	26	2.4	52	3.6	42	6.3	57	9.9	177	4.7
	Bronchoscopy abnormal, no purulent drainage	1	0.1	7	0.5	4	0.6	6	1.0	18	0.5
	Bronchoscopy abnormal, purulent drainage	1	0.1	9	0.6	7	1.1	3	0.5	20	0.5
	Bronchoscopy use not reported	1042	96.0	1343	92.9	605	91.0	505	87.7	3495	92.7
Left Lung Chest X-Ray Abnormalities*	**No abnormalities**	23	2.1	57	3.9	39	5.9	50	8.7	169	4.5
	Yes, non-infiltrate	6	0.6	9	0.6	3	0.5	8	1.4	26	0.7
	Yes, upper-infiltrate	1	0.1	2	0.1	2	0.3	2	0.3	7	0.2
	Yes, mid-infiltrate	1	0.1	4	0.3	3	0.5	5	0.9	13	0.3
	Yes, lower-infiltrate	5	0.5	16	1.1	9	1.4	3	0.5	33	0.9
	Yes, lower, mid-infiltrate	.	.	4	0.3	1	0.2	1	0.2	6	0.2
	Yes, lower, mid, upper-infiltrate	7	0.6	10	0.7	3	0.5	2	0.3	22	0.6
	X-Ray use/outcome not reported	1042	96.0	1343	92.9	605	91.0	505	87.7	3495	92.7
Right Lung Bronchoscopic Abnormalities and Purulent Drainage*	**Bronchoscopy not done**	18	1.7	31	2.1	10	1.5	9	1.6	68	1.8
	Bronchoscopy normal	26	2.4	54	3.7	42	6.3	46	8.0	168	4.5
	Bronchoscopy abnormal, no purulent drainage	3	0.3	6	0.4	5	0.8	10	1.7	24	0.6
	Bronchoscopy abnormal, purulent drainage	2	0.2	12	0.8	10	1.5	7	1.2	31	0.8
	Bronchoscopy use not reported	1036	95.5	1342	92.9	598	89.9	504	87.5	3480	92.3
Left Lung Chest X-Ray Abnormalities*	**No abnormalities**	24	2.2	60	4.2	42	6.3	47	8.2	173	4.6
	Yes, non-infiltrate	4	0.4	10	0.7	4	0.6	8	1.4	26	0.7
	Yes, upper-infiltrate	3	0.3	4	0.3	3	0.5	.	.	10	0.3
	Yes, mid-infiltrate	3	0.3	5	0.3	2	0.3	4	0.7	14	0.4
	Yes, lower-infiltrate	6	0.6	13	0.9	12	1.8	8	1.4	39	1.0
	Yes, lower, mid-infiltrate	1	0.1	3	0.2	1	0.2	2	0.3	7	0.2
	Yes, lower, mid, upper-infiltrate	8	0.7	8	0.6	3	0.5	3	0.5	22	0.6
	X-Ray use/outcome not reported	1036	95.5	1342	92.9	598	89.9	504	87.5	3480	92.3
History of Prior MI**	**N**	473	43.6	880	60.9	426	64.1	401	69.6	2180	57.8
	Y	19	1.8	26	1.8	13	2.0	11	1.9	69	1.8
	U	593	54.7	539	37.3	226	34.0	164	28.5	1522	40.4

K-21

		Match/offer type								All	
		Match was not run		Match was run*		Only Local offers		Zone A/B/C offers			
		N	%	N	%	N	%	N	%	N	%
Coronary angiogram**	**Abnormal**	14	1.3	29	2.0	12	1.8	12	2.1	67	1.8
	Normal	62	5.7	113	7.8	60	9.0	60	10.4	295	7.8
	Not done	383	35.3	714	49.4	339	51.0	321	55.7	1757	46.6
	Use/outcome not reported	626	57.7	589	40.8	254	38.2	183	31.8	1652	43.8
Right Heart Catheterization**	**N**	447	41.2	802	55.5	396	59.5	366	63.5	2011	53.3
	Y	48	4.4	105	7.3	43	6.5	47	8.2	243	6.4
	U	590	54.4	538	37.2	226	34.0	163	28.3	1517	40.2
Myocardial Biopsy**	**N**	436	40.2	806	55.8	378	56.8	366	63.5	1986	52.7
	Y	.	.	3	0.2	1	0.2	1	0.2	5	0.1
	U	649	59.8	636	44.0	286	43.0	209	36.3	1780	47.2

* Data submission is not required when neither lung was recovered.

** Currently, data submission for these items is not mandatory when the heart was not recovered. These fields will be required for all deceased donors in May 2004.

Table 7. Continuous donor characteristics

	Match was not run (N = 1085)					Match was run (N = 1445)					Only local offers (N = 665)				
	N	Mean	Std Error	10th %ile	90th %ile	N	Mean	Std Error	10th %ile	90th %ile	N	Mean	Std Error	10th %ile	90th %ile
Donor age	1085	38.3	0.4	20.0	53.0	1445	36.0	0.3	20.0	51.0	665	36.6	0.5	20.0	52.0
BMI (kg/m²)	1085	27.1	0.2	20.7	35.3	1445	28.6	1.5	20.3	33.9	665	25.8	0.2	20.5	32.8
Terminal Serum Creatinine	1077	1.5	0.0	0.6	2.5	1441	1.3	0.0	0.6	1.9	660	1.3	0.0	0.6	1.8
Terminal BUN	1079	18.3	0.5	6.0	33.0	1442	14.5	0.3	5.0	25.0	660	14.8	0.5	6.0	26.0
Terminal Total Bilirubin	1033	1.2	0.1	0.3	2.0	1400	1.1	0.0	0.3	2.0	656	1.0	0.0	0.3	1.8
Terminal SGOT/AST	1037	111.9	7.8	20.0	221.0	1404	131.7	15.3	20.0	173.0	656	109.9	16.9	20.0	152.0
Terminal SGPT/ALT	1036	97.5	7.3	15.0	178.0	1403	99.8	9.7	15.0	135.0	657	89.8	10.7	15.0	145.0
PO_2 on 100% O_2**	46	208.6	20.0	66.0	436.0	111	265.0	13.2	95.0	456.0	70	281.7	15.4	95.5	449.5
LV Ejection Fraction*	400	59.0	0.6	45.0	70.0	820	58.6	0.4	45.0	70.0	402	58.3	0.6	45.0	70.0
CVP*	41	10.4	0.8	4.0	16.0	101	9.2	0.4	5.0	14.0	35	8.7	0.6	4.0	14.0
PA Diastolic*	37	18.0	1.4	8.0	34.0	81	20.4	1.0	11.0	35.0	29	14.4	0.9	8.0	20.0
PA Systolic*	36	36.2	4.6	20.0	44.0	80	45.6	3.9	21.0	110.0	30	28.8	3.2	20.0	37.0
PCW*	28	13.5	1.1	7.0	21.0	76	11.6	0.5	7.0	18.0	27	10.5	0.9	5.0	17.0
Cardiac Output*	27	7.5	0.5	4.0	11.1	80	7.0	0.3	4.8	10.9	25	7.2	0.6	3.1	11.6

	Zone A/B/C Offers (N = 576)				
	# with Data	Mean	Std Error	10th %ile	90th %ile
Donor age	576	36.6	0.5	20.0	52.0
BMI (kg/m²)	576	26.0	0.2	20.0	33.4
Terminal Serum Creatinine	576	1.2	0.0	0.6	1.8
Terminal BUN	575	13.6	0.4	5.0	23.0
Terminal Total Bilirubin	570	1.0	0.1	0.3	2.0
Terminal SGOT/AST	572	109.2	13.6	18.0	156.0
Terminal SGPT/ALT	571	94.4	12.8	15.0	132.0
PO_2 on 100% O_2**	79	356.1	14.5	150.0	538.0
LV Ejection Fraction*	364	59.5	0.6	46.0	70.0
CVP*	41	9.1	0.6	4.0	13.0
PA Diastolic*	31	15.6	1.2	9.0	22.0
PA Systolic*	30	27.9	1.4	18.0	40.5
PCW*	29	12.2	0.9	6.0	19.0
Cardiac Output*	27	7.2	0.4	4.7	9.8

* Currently, data submission for these items is not mandatory when the heart was not recovered. These fields will be required for all deceased donors in May 2004.

** Data submission not required when neither lung was recovered.

K-23

OPTN/SRTR Data Working Group
Additional Transplant Endpoints
Summary Proposal

Background

To date, in order to evaluate the benefits of transplantation, the transplant community has been focused on patient and graft survival rates as the transplant outcomes of most interest. However, there are many other outcomes, commonly referred to as "additional transplant endpoints" that may be useful, either for the purpose of developing allocation algorithms or for assessing transplant system/program performance, or for both. For example, there may be some instances, such as in kidney and lung transplantation, where improving patient quality of life and functional status, rather than or in addition to prolonging life or patient survival, may play a role in the ultimate decision to receive an organ. Those who are involved in allocation policy development may wish to incorporate knowledge of relative degree of benefit in areas other than simply length of life into their decision making process. Such decisions should probably not be made entirely based upon data regarding death and graft survival, but also upon other outcomes data.
Therefore, the ultimate goal for exploring additional transplant outcome measures, is to enable the OPTN committees to consider them during the course of policy development, analyses and perhaps identifying patients who can most benefit from transplantation.

The OPTN/SRTR Data Working Group (DWG) would like to present this summary proposal to the Data Advisory Committee as well as other OPTN committees involved in allocation policy for their discussion and feedback.

Categories of Outcomes

In their meeting on April 3, 2003, members of the DWG identified major categories of additional endpoints, shown in the diagram below, that may be useful in evaluating the role of transplantation in decreasing patient morbidity and burden of disease, thereby improving patient quality of life and functional status.

Major categories of outcomes or Additional Transplant Endpoints

A	B	C	D	E
Mortality	**Morbidity**	**Disability**	**Psychological Distress**	**Resource Use**
	*Heart Attacks	*Pain and Suffering	*Anxiety	*Inpatient and ICU Hospitalizations
	* GI bleeds	*Functional Status	*Depression	*Ambulatory Care
	*Other Events Requiring Hospitalization			

These categories of outcomes are highly correlated, and information about one will yield information about the others.

Methodology to Obtain Data on Additional Transplant Endpoint

Morbid events and use of resources: These can be measured fairly objectively by analyses of patient hospitalization data before and after transplantation. The Data Working Group recognizes, that although the current OPTN data on post transplant hospitalizations are valuable and of good quality, these data alone are not collected in sufficient detail to allow optimal analyses. In addition, the collection of hospitalization data in the OPTN/UNOS database is limited currently to the post-transplant period; information regarding hospitalizations while patients are on the waiting list is not available. Also, transplant programs following patients may not be aware or may not provide information regarding hospitalizations at other hospitals. Therefore, additional

and independent sources of data with more comprehensive patient hospitalization information are essential for conducting valid studies of resource utilization.
The DWG has identified two possible additional sources of data for obtaining more comprehensive inpatient hospitalization data:

a) CMS data: Available only for kidney and kidney pancreas patients with Medicare as their primary insurance carrier. A proposal has been submitted by the DWG to HRSA to obtain patient identified hospitalization data for a cohort of Medicare beneficiaries on the national waiting list for a renal transplant.

b) Hospitalization data from state registries: These registries are maintained by non-profit agencies affiliated with the Department of Health in each state and have inpatient and sometimes outpatient level discharges, hospital and nursing facility cost and utilization, and facility demographic and administrative databases and reports, available for public use. Formal data requests and proposals have been submitted by UNOS and negotiations are currently underway with the states of Virginia and Pennsylvania, which have expressed some interest in providing patient identified hospitalization data for a cohort of transplant candidates and recipients in their states.

Disability and Functional Status: Health Related quality of life and functional status represent a dimension of outcomes which aim to measure an individual or a group of patients' own perceptions of health and ability to function on a daily basis. Data collected on these measures may be used in conjunction with measures of resource use and morbid events to evaluate the overall impact of transplantation on reducing burden of illness.

A Functional Status subcommittee of the DWG was formed to assess the quality of the data and validity of the current mechanisms by which data on functional and employment status are gathered and reported by the transplant centers to the OPTN. Based on reports provided by UNOS and SRTR staff the sub-committee and later on, the full committee concluded that the OPTN data on functional and employment status are valuable and should continue to be collected. However, the subcommittee also agreed that in order to have an accurate assessment of the role of transplantation on patients physical well being, daily activities and overall quality of life, it is important to collect data directly from patients rather than providers, using a randomly selected cohort of patients as a sample.

In their meeting on September 9, 2003, members of the Data working Group unanimously approved the Functional Status subcommittee's proposal to implement a pilot study to collect functional status and quality of life data directly from patients, by conducting a survey of a randomly selected cohort of patients, using a health related quality of Life questionnaire.

The main objectives of the pilot study were identified as follows:
1) To obtain epidemiological data on functional status which may be poorly represented at this time, in order to fill in the gap with respect to resource use and hospitalization.
2) To study the co-linearity among the outcome measures and whether they are largely independent of each other.
3) To be able to ultimately predict the expected outcome of a particular patient, in relation to different treatment interventions.

The general consensus was that it would be best if the pilot study were conducted by the OPTN, perhaps under the auspices of the Data Working Group, rather than by outside agencies such as NIH. Three main options were discussed for the administration of the study 1) NIH type, clinical trial experimental study model, where the OPTN would ask a sample of transplant centers to oversee the completion of a quality of life survey questionnaire by their patients and also administer a functional status scale such as the Karnofsky scale, on each patients at various times during a patient's evaluation, treatment and follow-up. 2) Direct patient contact model, where

the OPTN would obtain address and or phone numbers of a randomly selected sample of patients from their transplant centers, and either mail the patients a questionnaire or ask them to complete the survey by calling them on the phone. 3) Field staff model, where trained data collectors from primary sampling units located at various geographic areas throughout the country would actually visit the patients in their homes and administer a questionnaire and a Karnofsky scale at the time of their meeting. There are a number of survey research firms that employ these types of field staff with specific training in administering survey instruments.

The subcommittee agreed that model number two might be the best implementation approach, although option three was not entirely excluded. Each option may require individual patient consent and institution specific IRB approval from the centers. HRSA representatives to the DWG, agreed to investigate whether it would be possible to obtain a general IRB exemption from the Office of Human Research and Protection, which would cover the data elements collected through the pilot study by the OPTN.

Three sub-groups were formed: a) a survey instrument subgroup responsible to identify a questionnaire to be used in the pilot study, b) a statistical sub-group to develop a comprehensive analytical/statistical plan for the study, including the sample size, method of random sample selection and other analytical issues related to the survey and c) a scientific sub-group responsible for the scientific oversight of the study.

The study cohorts would include a sample of transplanted patients and patients on the waiting list who have not yet been transplanted, from each organ type. Transplanted patients would be surveyed at four time intervals: 1) baseline (immediately before transplant), 2) one month 3) six months and 4) one year. Patients not yet transplanted would be surveyed at 1) baseline (at time of wait list registration), 2) lesser of six months or median time to removal from the wait list and 3) twice the amount of time at time point 2.

Duration of the Study

The study will aim to be completed within three years.

Request 1

UNOS

Wait Time Modification Form

(UNOS Policy 3.2.1.8)

Date 8-18-2003 Organ Wait List HEART

Patient Name [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided)

[redacted]

Name of Transplant Center and UNOS Center Code [redacted]

[redacted]

54

Current Listing Date 8-18-2003

Listing Date Requested 6/25/2003

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation) Patient was requested to be listed & thought listed. Confirm with [redacted] HOSPITAL call book, on 6/25/2003.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain Yes- Documentation to be placed on chart from UNOS- pt successfully Inserted Candidate registration.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example.

Additionally, I: (must check one)

- O Patient Selection Minutes
- O Organ Justification Form, if Applicable
- O Patient Listing Confirmation Letter
- ⊗ Other (Please Specify) [redacted] HOSPITAL Call Book + STATUS LIS

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person [redacted]

Phone [redacted] email [redacted]

Physician/Surgeon Signature [redacted]

Physician /Surgeon Name (please print or type) [redacted]

Fax to: (804) 697-4372 Contact: Jim Creger (804) 782-4744

Or mail to: UNOS Organ Center, 700 N[redacted] 4th Street PO Box 2484, Richmond, Virginia, 23218

rev. January 2003

EXHIBIT M

924827 Heart Call Book

Name: [redacted] Listed 6/25/03 **MR #** [redacted] **SSN #** [redacted] Heart
Address: [redacted]
City: [redacted] **Physician:**

Age 59

Weight: 6/25/03 218 Lbs. **ABO:** O+

Home Phone [redacted]
Cell Phone [redacted]

Height: 6/25/03 75 Inches

CMV IGG: 4/7/2003 22 **Range**
CMV IGM: 4/7/03 NEGATI\ **Travel Time** 2 Hr(s)
Allergies NKA **PRA:** 4/7/03 4

Coumadii		Amiodarone		Primacor		Doubtrex		Flolan	
Start	Stop	Start	Stop	Start	Stop	Start	Stop	Start	Stop
				6/25/03	6/25/04	6/25/03	1/1/00		

Previous Surgeries

1996- Mitral Valve Replacement- St Jude Medical.
January 2003 - AICD Placement- Medtronic

Cardiac Cath: **EF:**

Native	**L Main:** Patent	**LAD:** 61-80%	**RCA:** Patent	**LCX:** Patent
Grafts	**L Main:**	**LAD:**	**RCA:**	**LCX:**
	MV: None	**TR:** Severe	**AI:** None	

Comment

Echo:
9/24/02 **EF** 20 %
LV Severe left ventricular enlargement, moderate to s **Valve** The aortic and tricuspid valves appear to be struct

Max VO2 3/6/03 15.0

TLC 6.75

Status 1B 6/25/03
Diagnosis Ischaemic cardiomyopathy
Valvular cardiomyopathy

PA Pressures

PA Sys	PA Dia	PA Mean	CO	PVR	PCWP	Condition
6/11/03 46	6/11/03 20	6/11/03 31	6/11/03 5	12/12/0 1.00	6/11/03 18	6/11/03
12/12/02 53	12/12/0226	12/12/02 38	12/12/0 6	6/11/03 2.82	12/12/02 30	12/12/0

Lung Needed:

Lung Scan

Comments 06/25/03 AICD-MEDTRONIC

Adjust Waiting Time for Heart Candidate

Successfully adjusted waiting time

Back Update

Provider Information

Transplant Center: [redacted]
24 Hour Contact Phone Number: [redacted]

Requested By:

Demographic Information for Candidate SSN: [redacted]

Name: [redacted]
DOB: [redacted]

List Date: 08/18/2003 13:38:26
Gender: M

Previous UNOS Waiting Time By Status (Days Hrs:Min:Sec)

Status	Accumulated Time	Adjustment	Adjusted Accumulated Time
1A - Status 1A	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0
1B - Status 1B	0 days 0:0:0	54 days 0:0:0	54 days 0:0:0
2 - Status 2	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0
7 - Temporarily inactive	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0

Inactive Heart Program Penalty Time History for [redacted]

Inactive Date	Penalty Date	Reactivate Date	Inactive Penalty Days
No Inactive Penalty Time Found			

Heart Waiting Time Information

Status to Adjust:
Amount of Time to Adjust: Days Hours Minutes
Is this a Backdate? Yes No
If not backdating, then select one of the candidate's previous statuses:

Back Update

Public Burden/Privacy Act Statements

Request 2

UNOS

Wait Time Modification Form

(UNOS Policy 3.2.1.8)

Date 3-10-2003 Organ Wait List Lung

Patient Name [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided)

401-76-1003

Name of Transplant Center and UNOS Center Code [redacted]

Current Listing Date 6-10-2003

Listing Date Requested 6-26-2003

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation) Patient was requested to be listed on UNOS waiting list & thought listed on UNOS. Confirmed [redacted] and Body date listed 6/22/2003.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain Pkg - Documentation to be placed on chart from UNOS. Patient surveyship Initiated Candidate Reg Station

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example.

Additionally, I: (must check one)

- O Patient Selection Minutes
- O Organ Justification Form, If Applicable
- O Patient Listing Confirmation Letter
- ⊗ Other (Please Specify) [redacted] Care Board + STATUS LIST

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person [redacted]

Phone [redacted] email [redacted]

Physician/Surgeon Signature [redacted]

Physician /Surgeon Name (please print or type) [redacted]

Fax to: (804) 697-4372 Contact: Jim Creger (804) 782-4744

Or mail to: UNOS Organ Center, 700 North 4th Street, PO Box 2484, Richmond, Virginia, 23218

rev. January 2001

[redacted]

Request 1 and 2

Attachment
UNOS Time Modification Form [redacted]

Other Local Transplant Center:

University of [redacted]

University of [redacted] Hospital Transplant Center approves [redacted] Hospital Transplant Center's request to modify the waiting times of [redacted] and [redacted] as outlined in the UNOS Wait Time Modification Forms attached.

Signature: [redacted]

Date: 10/29/03

[redacted], Director, Transplant Services

[redacted]

Request 3

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 11-7-03 **Organ Wait List:** Lung

Patient Name: [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided): [redacted]

Name of Transplant Center and UNOS Center Code: [redacted]

Current Listing Date: 11/6/03

Listing Date Requested: 9/18/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): Pt was entered into Unet for listing on 9-18-03 and I didn't continue on to next page so pt never got listed. Pt is current on [redacted] on 40-50% O2 mask so his time is crucial in that he doesn't have but a few months to live

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: This was an error on my part as the screen was new and I didn't continue on to the next page. To make sure that I see pt satisfactory inserted Candidate Registration

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- **Patient on dialysis, or**
- **Measured (actual urinary collection) creatinine clearance level or calculated GFR <= 20 ml/min.**

Appropriate documentation is required. **Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:**

- ☐ Patient Selection Minutes
- ☐ Organ Justification Form, if Applicable
- ☐ Patient Listing Confirmation Letter
- ☐ Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: [redacted]

Physician/Surgeon Signature: [redacted]

Physician/Surgeon Name: [redacted]
(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

[redacted]

[redacted]

NOV-10-2003 20:29

REQUEST 3

Attachment
UNOS Time Modification Form
[redacted]

Other Local Transplant Center:

University of [redacted]

University of [redacted] Hospital Transplant Center approves [redacted] Hospital Transplant Center's request to modify the waiting time of [redacted] as outlined in the UNOS Wait Time Modification Forms attached.

[redacted] Director, Transplant Services — 11/10/03 Date

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 10/14/03 **Organ Wait List:** HEART

Patient Name: [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided):
SS# [redacted]

Name of Transplant Center and UNOS Center Code: [redacted]

Current Listing Date: 10/10/2003

Listing Date Requested: 10/2/2003 ext'n due 10/3/03. with

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): This was to be her 2nd week as ~~to~~ 1-D I did modify the form on 10/2/03 thinking I was re-certifing her her PA Pressures 58/25 wedge-24 on .5 Primacor Ventricular Ectopy PA Sat 34.1% (10/1/03)

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- **Patient on dialysis, or**
- **Measured (actual urinary collection) creatinine clearance level or calculated GFR </= 20 ml/min.**

Appropriate documentation is required. **Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:**

- ☐ Patient Selection Minutes
- ☐ Organ Justification Form, if Applicable
- ☐ Patient Listing Confirmation Letter
- ☐ Other (Please specify) _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: [redacted]

Physician/Surgeon Signature: [redacted]

Physician/Surgeon Name: [redacted]

(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

October 17, 2003

Center [redacted], coordinator [redacted] is requesting Status 1A time from 10/3/03 to 10/10/03 for patient [redacted] ssn [redacted] claiming there was a technically glitch in UNet[sm] and the patient's extension form was lost. Please let me know the outcome of this request.

Thank you,
Rachel Hailey
Heart Compliance Examiner
Policy Compliance Department
Ext. 4661

Adjust Waiting Time for Heart Candidate

Successfully adjusted waiting time

Back Update

Provider Information

Transplant Center: [redacted]
24 Hour Contact Phone Number: [redacted]

Requested By:

Demographic Information for Candidate SSN: [redacted]

Name: [redacted]
DOB: [redacted]

List Date: 09/26/2003 13:14:08
Gender: F

Previous UNOS Waiting Time By Status (Days Hrs:Min:Sec)

Status	Accumulated Time	Adjustment	Adjusted Accumulated Time
1A - Status 1A	14 days 11:19:36	7 days 0:0:0	21 days 11:19:36
1B - Status 1B	6 days 16:34:18	0 days 0:0:0	6 days 16:34:18
2 - Status 2	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0
7 - Temporarily inactive	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0

Inactive Heart Program Penalty Time History for [redacted]

Inactive Date	Penalty Date	Reactivate Date	Inactive Penalty Days
No Inactive Penalty Time Found			

Heart Waiting Time Information

Status to Adjust:
Amount of Time to Adjust: Days Hours Minutes
Is this a Backdate? Yes No
If not backdating, then select one of the candidate's previous statuses:

Back Update

Public Burden/Privacy Act Statements

#1

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: March 29, 2004 **Organ Wait List:** Lung

Patient Name: [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided):

Name of Transplant Center and UNOS Center Code:
IN [redacted] LA1

Current Listing Date: initially 7/23/03, inactivated 7/29/03, reactivated 3/27/04

Listing Date Requested: 8/26/03

214

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): The RN went into the UNOS Computer on 8/26/03 to "reactivate" the patient (on 8/26/03) but instead she did not make the appropriate choice (active vs. inactive) therefore the patient remained inactive when our team "thought" she had been active since then. We have been following her as an outpatient in our clinic since that time.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: Yes - for all patients that are currently listed, these will be reviewed for accuracy ASAP. The policy will be updated so that the lists (~~UNOS~~ our program specific waiting list and the [redacted] wait list) are checked every week.

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- **Patient on dialysis, or**
- **Measured (actual urinary collection) creatinine clearance level or calculated GFR </= 20 ml/min.**

Appropriate documentation is required. **Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:**

- ☐ **Patient Selection Minutes**
- ☐ **Organ Justification Form, if Applicable**
- ☐ **Patient Listing Confirmation Letter**
- ☐ **Other (Please specify)** _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating

Transplant Center Contact Person: ___

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____
(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

* The only other [illegible] is the surgical director of that program as well.

July 15, 2003

Re:
ID#:

To Whom It May Concern:

The
has been consulted to review 's condition and need for possible Lung transplantation. After further investigation, we conclude that has end stage lung disease that is not amenable to conventional medical or surgical treatment. As a result, it is our recommendation that needs a lung transplant as the only option available for long term survival. She would benefit from either a single or double lung transplant.

Please review the attached medical information expeditiously so we may add her to the active waiting list as soon as possible. If you have any questions or need additional information please contact our office at

Sincerely,

Encl.

July 17, 2003

RE:

Dear

I wanted to give you some follow-up regarding She has completed her pretransplant evaluation. It was the decision of the transplant committee to list for a single lung transplant.

During her evaluation, she was found to have several 2 mm nodules in her left lung, which are likely nonspecific. However, she will need to have a follow-up CT scan in approximately six months. She was also found to have significant osteoporosis and we would recommend that she begin treatment with Actonel 35 mg per week along with calcium supplement.

While she is on the transplant list it is imperative that she participate in a pulmonary rehabilitation program. Your help in facilitating her participation in such a program would be appreciated. Lastly, was found to have a significant elevation in her serum cholesterol. We would also recommend that she be treated with a lipid lowering agent.

Again, thank you for referring to the transplant program. We will keep you updated regarding her transplant status. We would appreciate notification of any significant change in her clinical status.

Please let me know if I can provide you with any additional information.

Sincerely,

cc:

August 21, 2003

Re:

Dear

I am pleased to inform you that meets our established criteria and was accepted as a candidate for lung transplantation by our Cardiothoracic Transplantation Committee. She was placed on the waiting list on July 23, 2003.

Our office will follow her periodically in our pre-transplant clinic and will send you correspondence from each pre-transplant visit. We request that you keep us updated on her condition, as well, especially in regards to any hospital admissions she may have. I am enclosing copies of her evaluation testing for your records.

As her primary care physician, we ask your assistance with the following:

serology studies showed her to have no prior exposure to Hepatitis B. In order to keep our patients from acquiring Hepatitis B from their transplanted organ it is imperative that they receive a series of hepatitis B vaccines. We would suggest administering an accelerated series given at months 0, 1, 2, and at month 12. We also suggest administering a prophylactic Pneumovax if this has not previously been done. Please send us confirmation once these immunizations have been initiated.

If you have additional questions please contact our office at . Thank you for your kind support of our transplant program.

Sincerely,

Encl.

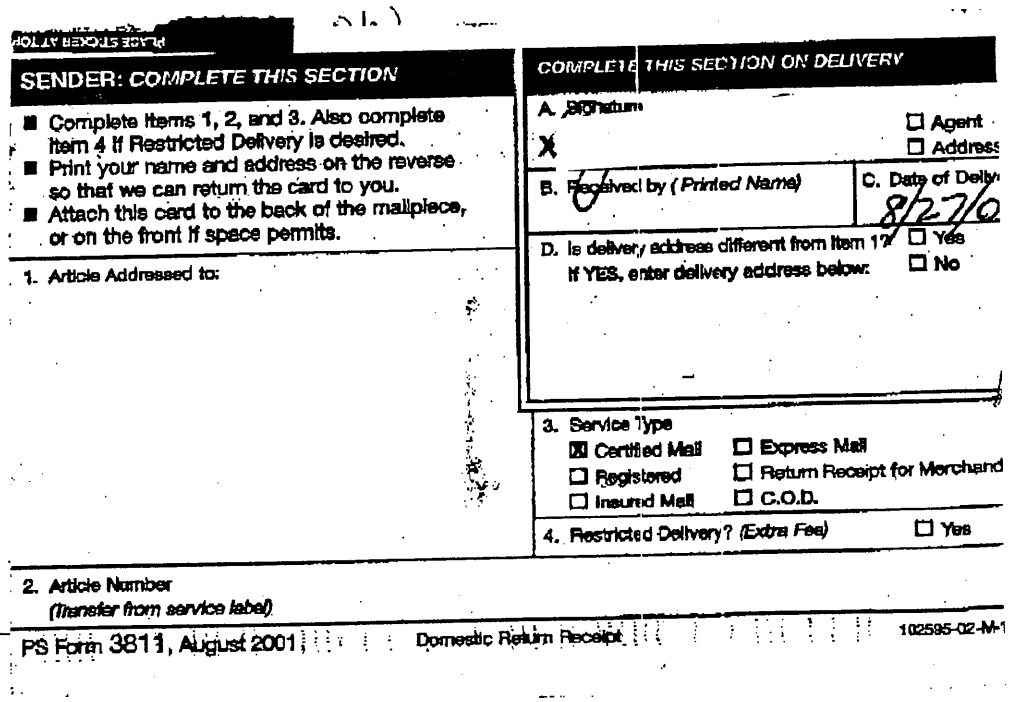
August 21, 2003

Dear '

This letter serves as an official notification that you were placed on the UNOS Waiting List on July 23, 2003. Your serology studies performed during evaluation indicate no prior exposure to Hepatitis B. Therefore it is necessary for you to receive the Hepatitis B vaccines. We also suggest administering a prophylactic Pneumovax if this has not previously been done. Please send us confirmation once these immunizations have been initiated.

Should you have any questions regarding your listing please contact our offices at

Sincerely,



SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X
☐ Agent
☐ Address

B. Received by (Printed Name)

C. Date of Deliv
8/27/0

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchand
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number
(Transfer from service label)

PS Form 3811, August 2001 Domestic Return Receipt 102595-02-M-1

August 22, 2003

20

Re: C

Dear

Congratulations! You are on the waiting list for lung transplantation. You are now required to attend pre-transplant clinic periodically, so that we may stay up-to-date with your health status. The following is an outline of our expectations of you in relation to those clinic visits.

It is extremely important that you adhere to this schedule. This will be your ONLY notice, so do not lose this letter! If circumstances prohibit you from coming on your assigned day, you must notify this office as soon as possible at

1. **Pre-transplant clinic is held on Thursday afternoons. Your assigned clinic days will be the SECOND Thursday of February, June and October.** Your first clinic will be October 9, 2003.

2. Our new clinic is located on the 1st floor of the new I Street (across). **Please go to the** , on the second floor of the I to sign in. Turn right when you leave the elevators.

3. There is a **pre-transplant support group meeting** at 12 noon, immediately preceding each clinic, in the 1. The physical therapist will also be present to perform six-minute walks at this time.

4. During each visit, **the physical therapist will perform six-minute walks for everyone.** Be sure to complete this necessary test before you leave!

5. After the support group, **transplant clinic will be in** on the first floor of the here you will see the coordinator and the pulmonologist.

Hear

6. **Every clinic visit you will have lab tests and sputum collected for cultures.** Both of these are done at t... located on the 3rd floor of the

7. **Chest x-rays** will be done periodically. You will be notified if one is needed. Radiology is located on the 1st floor of the

8. If you should ever require a **right heart catheterization**, do not take any aspirin, Coumadin, Persantine or Ticlid for 72 hours (3 days) prior to the scheduled day of the procedure. You will receive further instructions regarding this procedure, if it should be necessary.

9. If you determine that you would like to stay at e, please notify me as soon as possible. This facility is only available for transplant patients who live more than 50 miles away from As always, their space is limited and it's helpful to get the request for your reservation in early.

10. **It is imperative that you remember to obtain any and all referrals and or pre-certifications that your insurance carrier may require before your clinic visits.** If there is something that we need to do to complete that process, please let us know.

Put this schedule in a safe place and refer to it for any question you may have regarding your clinic visits. You will be expected to follow everything that is outlined above, without further reminders from this office.

If you do have any questions, please call me at

Sincerely,

TO WHOM IT MAY CONCERN:

RE:

I am the owner of a

Please let this letter serve as my permission and direction that
if and when a lung becomes available for transplant for
that my airplane will be available to transport her t
the airport closest to your medical facility, subject to availability.

Please call one or any of the following pilots when this
transplant becomes available:

entered under contacts

The above pilots are my employees.

Thank you.

Yours very truly,

ben

xc:

FAXED TO

Fax No.:

VIA FAX

August 26, 2003

Attn:

To Whom It May Concern:

RE: Transportation for [redacted]

We have been contacted by [redacted] requesting transportation from [redacted] when she is notified that a lung is available for her transplant.

We will be pleased to offer [redacted] this service on our privately owned plane which is a 1982 [redacted] 1 550. We have a Chief Pilot and a Co-Pilot on staff who are available to us by telephone at [redacted] Monday thru Friday, 8:00 am to 5:00 pm and cell phone [redacted] on a 24-hour basis. We should be able to transport [redacted] unless any or all of the following conditions exist:

a. the plane is out of town on other business;

b. the plane is unable to fly due to mechanical difficulties;

c. the plane is unable to fly due to adverse weather conditions; and

d. any other unforeseen conditions which would prevent the plane from flying safely.

Sincerely,

[redacted]

Q-11

August 27, 2003

RE:

Dear .

has agreed to fly . within three (3) hours of her transplant notification.

He can be reached at the following telephone numbers: w
phone .

Sincerely,

Q-12

October 09, 2003

RE: [redacted]

Dear

I had the opportunity to see [redacted] in the pretransplant clinic at [redacted]r. As you recall, she underwent evaluation for lung transplantation and has been placed on the waiting list at [redacted]ter. Since her evaluation, there has not been a major change in her clinical course. She continues to work full time, however, is not performing any form of rehab. She has not required any recent prednisone therapy.

On exam, her oxygen saturation was 94% on 2 liters of supplemental oxygen. Lung exam was clear without wheezing. Cardiovascular exam revealed a regular rate and rhythm. Abdomen was soft, positive bowel sounds. Extremities revealed no edema.

She underwent a six-minute walk and was able to ambulate 988 feet with oxygen desaturation down to 90% on 2 liters of supplemental oxygen. Her six-minute walk distance has improved from April when she ambulated 840 feet.

From a pulmonary standpoint, I feel [redacted] is relatively stable, but clearly in need of transplantation. I reviewed with her the risks and benefits of transplant. In addition I emphasized the importance of daily rehab, as well as close monitoring of nutritional status.

Of note, during her evaluation, she was found to have a nonspecific pulmonary nodule on CT scan. We plan to repeat a CT scan on her next follow-up visit for comparison.

We will keep you updated, however, if there are any questions, please do not hesitate to contact me.

Sincerely,

[redacted]

cc:

March 29, 2004

Re:
SSN

To Whom It May Concern:

We are asking you to please review her case and modify
time on the active lung transplant waiting list.

was inadvertently "inactivated" on August 26, 2003. This date should have been her reactivation date. We have provided documentation to support this request.

We would appreciate your immediate attention to this matter so may be transplanted next time an organ is offered to her.

Sincerely,

March 29, 2004

Re: [redacted]
SSN:

To Whom It May Concern:

We are asking you to please review her case and modify [redacted] time on the active lung transplant waiting list.

[redacted] was inadvertently "inactivated" on August 26, 2003. This date should have been her reactivation date. We have provided documentation to support this request.

We would appreciate your immediate attention to this matter so [redacted] may be transplanted next time an organ is offered to her.

Sincerely,

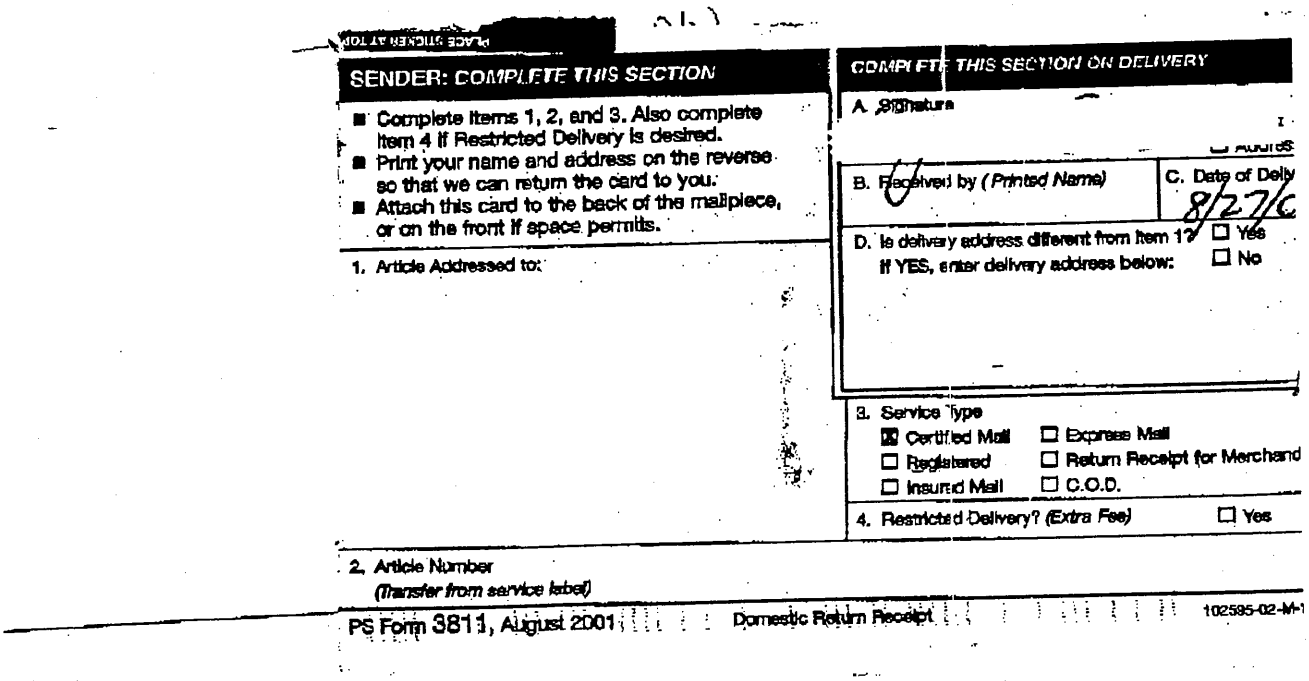
August 21, 2003

Dear

This letter serves as an official notification that you were placed on the UNOS Waiting List on July 23, 2003. Your serology studies performed during evaluation indicate no prior exposure to Hepatitis B. Therefore it is necessary for you to receive the Hepatitis B vaccines. We also suggest administering a prophylactic Pneumovax if this has not previously been done. Please send us confirmation once these immunizations have been initiated.

Should you have any questions regarding your listing please contact our offices at

Sincerely,



SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

COMPLETE THIS SECTION ON DELIVERY

A. Signature

B. Received by (Printed Name)

C. Date of Deliv 8/27/0

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchand
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number
(Transfer from service label)

PS Form 3811, August 2001 Domestic Return Receipt 102595-02-M-1

MAR-30-2004 10E

VIA FAX

August 26, 2003

Attn: [redacted]

To Whom It May Concern:

RE: Transportation for [redacted]

We have been contacted by [redacted] on requesting transportation from [redacted] when she is notified that a lung is available for her transplant.

We will be pleased to offer [redacted] this service on our privately owned plane which is a [redacted]. We have a Chief Pilot and a Co-Pilot on staff who are available to us by telephone at [redacted] Monday thru Friday, 8:00 am to 5:00 pm and cell phone [redacted] on a 24-hour basis. We should be able to transport [redacted] nless any or all of the following conditions exist:

a. the plane is out of town on other business;

b. the plane is unable to fly due to mechanical difficulties;

c. the plane is unable to fly due to adverse weather conditions; and

d. any other unforeseen conditions which would prevent the plane from flying safely.

Sincerely,

[redacted]

Q-18

October 09, 2003

RE:

Dear

I had the opportunity to see in the pretransplant clinic at As you recall, she underwent evaluation for lung transplantation and has been placed on the waiting list at Since her evaluation, there has not been a major change in her clinical course. She continues to work full time, however, is not performing any form of rehab. She has not required any recent prednisone therapy.

On exam, her oxygen saturation was 94% on 2 liters of supplemental oxygen. Lung exam was clear without wheezing. Cardiovascular exam revealed a regular rate and rhythm. Abdomen was soft, positive bowel sounds. Extremities revealed no edema.

She underwent a six-minute walk and was able to ambulate 988 feet with oxygen desaturation down to 90% on 2 liters of supplemental oxygen. Her six-minute walk distance has improved from April when she ambulated 840 feet.

From a pulmonary standpoint, I feel is relatively stable, but clearly in need of transplantation. I reviewed with her the risks and benefits of transplant. In addition I emphasized the importance of daily rehab, as well as close monitoring of nutritional status.

Of note, during her evaluation, she was found to have a nonspecific pulmonary nodule on CT scan. We plan to repeat a CT scan on her next follow-up visit for comparison.

We will keep you updated, however, if there are any questions, please do not hesitate to contact me.

Sincerely,

cc:

#3

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 1/22/04 **Organ Wait List:** Lung

Patient Name:

Patient Social Security Number or HIC Number (please specify which number is being provided):
Social Security #

Name of Transplant Center and UNOS Center Code:
UNOS Code

Current Listing Date: 1/15/04

Listing Date Requested: 1/24/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation):

See Attachment

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain:

See Attachment

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- **Patient on dialysis, or**
- **Measured (actual urinary collection) creatinine clearance level or calculated GFR </= 20 ml/min.**

Appropriate documentation is required. **Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:**

- ☐ **Patient Selection Minutes**
- ☐ **Organ Justification Form, if Applicable**
- ☑ **Patient Listing Confirmation Letter**
- ☐ **Other (Please specify)** _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating /

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____
(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

#1

had a transplant evaluation here, but completed pre-listing requirements at his local medical facility. He was to return here for follow up appointment, but had to reschedule twice due to family emergency.
He should have been listed on the lung transplant wait list when pre-listing criteria was met. Because he was unable to keep his appointments here, and finished tests in , the data was not pulled together and he was not placed on the list.

#2

Communication between the coordinator and patient was misunderstood and incomplete. E-mail had been used and some messages apparently not received. Our practice of communication has been reviewed, and written letter, or direct conversation with documentation will be enforced as the standard.

January 22, 2004

Now that you have completed your transplant work-up and have been accepted into the Thoracic Transplant Program at you have been placed on the Lung Transplant Waiting List as of 1. As you know, we have received approval from your insurance company for the procedure. It is important that you familiarize yourself with the details of your specific insurance policy. Our patient financial representative, available to assist you if you have questions regarding your coverage at

It is very important that we always have a current list of telephone numbers to easily locate you. If you are not available at telephone, you will need to carry a beeper or cell phone with you at all times. If you don't already have a beeper or cell phone, check with some of your local beeper and cell phone providers to see if they are willing to provide one at a reduced rate. If your beeper should go off, it is important to respond as soon as possible to the number displayed . This number is answered 24 hours a day/7 days a week. After hours please follow instructions provided on the recording. It is recommended that you attach this number to your beeper so that you have it with you at all times.

It is very important for you and your physician to keep us informed of changes in your medical condition as it may affect your status on the transplant list. Please inform us of any medication changes, blood transfusions, or any other changes in your state of health. We expect you to call us once per month to update us as to how you are doing.

When you are notified for your transplant, you will be given specific instructions of where to go and how long you have to get to the hospital. As discussed, you will need to arrive at within 2 – 2 ½ hours after you are notified.

We are pleased to have you on the transplant list. Please call us at with any questions.

Sincerely,

cc: See Attachment

1/22/2004

As we discussed on the phone on January 15th 2004, I am submitting a request for Wait Time modification to UNOS, to credit wait time for you back to January 24th 2003. I have been told it may take awhile for the request to be processed. You are active, accruing time now and I will let you know when I get any information about the added time. Have your clinic fax me your weight record, and please call if there are any additional updates, problems or questions.
I am sending a copy of this letter and attachment to UNOS, as it is part of the required information they need for the time modification.

Sincerely,

Time calculation

From: **Friday, January 24, 2003 00:00:00**
to: **Thursday, January 15, 2004 00:00:00**

It is 356 days, 0 hours, 0 minutes and 0 seconds between those date

Or 30758400 seconds or 512640 minutes or 8544 hours

Note: The calculation is performed using USA calendar system, and UTC-time, so no local seconds or daylight saving time is taken into consideration (may be one hour off real differe

Related links

- Date related services - overview
- Calculate important events to celebrate given your birthday
- Date-calculator, which day is it in 500 days?

Adjust Waiting Time for Lung Candidate

Successfully adjusted waiting time

Back Update

Provider Information

Transplant Center:
24 Hour Contact Phone Number:

Requested By:

Demographic Information for Candidate SSN:

Name:
DOB:

List Date: :46
Gender:

Previous UNOS Waiting Time By Status (Days Hrs:Min:Sec)

Status	Accumulated Time	Adjustment	Adjusted Accumulated Time
0 - Active	0 days 0:0:0	356 days 0:0:0	356 days 0:0:0
7 - Temporarily Inactive	0 days 0:0:0	0 days 0:0:0	0 days 0:0:0

Inactive Lung Program Penalty Time History for [redacted]

Inactive Date	Penalty Date	Reactivate Date	Inactive Penalty Days
No Inactive Penalty Time Found			

Lung Waiting Time Information

Status to Adjust:

Amount of Time to Adjust: Days Hours Minutes

Is this a Backdate? Yes No

If not backdating, then select one of the candidate's previous statuses:

Back Update

Public Burden/Privacy Act Statements

UNOS Organ Center Corrective Action Process

1. All organ placement, organ transportation, match requests and waitlist requests are audited retrospectively through prescribed processes (see Organ Center Procedures).

2. Errors in process or documentation are corrected by auditing staff and documented by the Quality Management staff in the Organ Center Quality Management database.

3. Errors related to policy are documented by the Quality Management staff in the Organ Center Quality Management database and brought to the attention of Organ Center Managers for review and potential immediate corrective action.

4. Monthly, the following processes occur:
    - Employee-specific quality management reports are generated and distributed in a confidential manner to each organ placement specialists for their review. Any questions or issues are to be addressed with the quality management staff. Quality management staff may recommend suggestions for corrective action and/or training. It is requested that the organ placement specialist sign and return the report to quality management staff to demonstrate that the employee has reviewed the information.
    - Monthly quality management managers meetings are held to review the volume and types of documented errors and to recommend corrective actions, such as departmental quizzes, bulletin boards, e-mails, handouts, and training sessions (departmental, individual).
    - Monthly quality management staff meeting are held with and interested group of volunteer staff to review the volume and types of documented errors and to recommend processes for implementing corrective actions.

5. In the month(s) following implementation of a corrective action, error rates for the identified problem will be compared with previous months to determine if the corrective action was effective. If not, other corrective actions will be developed in quality management managers and staff meetings and implemented quality management staff.

6. All corrective actions are documented for future reference.

FAX

(Second Fax)

4/20/04

Date: ~~4/22/04~~

TO: Jim Crieger

Phone: 804-782-4744

Fax: 804-697-4372

From:

Comments: I can be reached @ the above number, please call if any additional information is needed.

Thank you for your prompt attention to this matter.

Id

Total Number of Pages (including cover sheet): 6

☐ Immediate Action Requested ☐ For Review ☐ Please Reply ☐ Please Call When Completed

(#4

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: 12/23/03 **Organ Wait List:** Lung (bilateral)

Patient Name: [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided):
SS# [redacted]

Name of Transplant Center and UNOS Center Code: [redacted]

80

Current Listing Date: 12/23/03

Listing Date Requested: 10/20/03

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): Coordinator remembers listing patient on 10/20/03 - pt is not on list.

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: unsure of error - whether data did not enter correctly as computer error

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- **Patient on dialysis, or**
- **Measured (actual urinary collection) creatinine clearance level or calculated GFR <= 20 ml/min.**

Appropriate documentation is required. **Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:**

- ☐ **Patient Selection Minutes**
- ☐ **Organ Justification Form, if Applicable**
- ☒ **Patient Listing Confirmation Letter**
- ☐ **Other (Please specify)** _____

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: [redacted] NP

Physician/Surgeon Signature: [redacted]

Physician/Surgeon Name: [redacted] MD

(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

October 20, 2003

Ms. [redacted]

Dear Ms. Fields:

In keeping with the policy of the United Network for Organ Sharing, I am sending you this letter to confirm that you have been added to the list for bilateral lung transplant as we discussed. The date of listing is October 20, 2003.

If you have any questions, please give me a call.

Sincerely,

[redacted]

Maureen Flattery, ANP
Clinical Coordinator

#5

WAITING TIME MODIFICATION FORM
(OPTN/UNOS Policy 3.2.1.8)

Date: February 11, 2004 Organ Wait List: Lung

Patient Name: [redacted]

Patient Social Security Number or HIC Number (please specify which number is being provided):

Name of Transplant Center and UNOS Center Code: [redacted]

Current Listing Date: 5/9/03

~~Listing Date Requested~~: Request reinstatement of days from 6/20/03 - 2/4/04

Explanations for Request (please continue on additional pages as necessary and attach any supporting documentation): See Attached letter

If the request is due to an error, miscommunication, or similar cause, has any corrective action been taken to prevent future occurrences? Please explain: See Attached letter

If the request is to modify isolated kidney or combined kidney/pancreas waiting time, please indicate below that the candidate met criteria for waiting time accrual as of the listing date requested (please check applicable criteria). Your response to this question must be substantiated with supporting documentation.

- o Patient on dialysis, or
- o Measured (actual urinary collection) creatinine clearance level or calculated GFR </= 20 ml/min.

Appropriate documentation is required. Please Attach Any Additional Supporting Documentation. Such documentation (in addition to responses provided above) may include, for example:

- ☐ Patient Selection Minutes
- ☐ Organ Justification Form, if Applicable
- ☐ Patient Listing Confirmation Letter
- ☒ Other (Please specify) Internal transplant list dates 6/6/03 & 6/20/03 Transplant team agendas 6/12/03 & 6/26/03

Attach List of Local Transplant Centers, with Transplant Programs for the Applicable Organ, and Signatures of Each Center's UNOS Representative, Indicating Approval.

Transplant Center Contact Person: _____

Physician/Surgeon Signature: _____

Physician/Surgeon Name: _____ , MD

(Please Print or Type)

Please Fax to: 804-697-4372
Or Mail to: UNOS Organ Center, 700 North 4th Street, Richmond, VA 23219

- Doyle
- Leung
- Sung / Weinkauf
- Romero
- Russell
- Levin

HEART LUNG AND LUNG TRANSPLANT MEETING
THURSDAY, JUNE 12, 2003

I. DONOR OFFERS FOR WEEK:

II. NEW TRANSPLANTS IN-PATIENT: [redacted] DC 5/13/03

III. POST TRANSPLANTS/READMITS: [redacted] - sinusitis, bone erosion,

IV. NEW PATIENTS: Defer until next wk.
- [redacted] 50YO F; ALPHA-1
- [redacted] 12YO M; PPH

V. RETURN PATIENTS: [redacted] 54YO F; IPF – needs TP
LISTED 4/15/03 ACTIVE-*NEEDS IT YESTERDAY*

[redacted]) 43YO M; EISEN. AFib → OK not VEAs

VI. LIST UPDATE: [redacted] YO F; CF
ON HOLD FOR VACATION 6/7-6/19

VII. MISCELLANEOUS/REFERRALS:
- ☐ defer [redacted] 42YO F; PH/EMBOLIC
- ☐ defer [redacted] 13MO M; PH → AS, MS, 2° valvuloplasty, Ross-Konno, Yas rec'd. Tacoma 5/12/03 →
- ☐ defer [redacted] 57YO M; COPD/MYXOMA
- ☐ defer [redacted] 38YO M; LAM

NO attending surgeon

VIII. TRANSPLANT NETWORK REPORT:

HEART LUNG AND LUNG TRANSPLANT MEETING
THURSDAY, JUNE 26, 2003

UPDATE ON STATISTICS AND INTERNATIONAL LISTINGS-

I. DONOR OFFERS FOR WEEK:

II. NEW TRANSPLANTS IN-PATIENT: [redacted] REDO BL 6/25/03

III. POST TRANSPLANTS/READMITS: [redacted]

IV. NEW PATIENTS:

[redacted] 18YO F; PPH - HL

[redacted] YO F; EISEN.

[redacted] F; PF — list BL

[redacted] 50YO F; ALPHA-1 — BL ± bullae

[redacted] 12YO M; PPH BL

V. RETURN PATIENTS:

[redacted] 0YO F; LAM

[redacted] 20YO F; CF good
LISTED BL 5/9/03 ACTIVE

[redacted] 33YO F; EISENMENGERS

[redacted] 44YO M; ALPHA1/ BRONCHIECT good
LISTED BL 1/6/03 ACTIVE

[redacted] 12YO F; CF
LISTED BL 12/6/01 INACTIVE VACATION

[redacted] 65YO M; IPF
LISTED EL 6/1/01 INACTIVE-TOO WELL

[redacted] CF

VI. LIST UPDATE:

VII. MISCELLANEOUS/REFERRALS:

[redacted] INTERNATIONAL REFERRAL

[redacted] 53YO M; IPF

Date: 6/6/03
To: Transplant Team
From:

HEART/LUNG AND LUNG TRANSPLANT CANDIDATES

ACTIVE

Blood Group A ORG	Patient Name	Sta	AGE	DATE ACCEPTED	DX	Ht.	Wt. (lbs.)	CMV
BL	Pt away 6/7-6/19/03	hold	20	5/9/2003	Cystic Fibrosis	5' 1"	101	Pos.

Blood Group AB ORG	Patient Name	Sta	AGE	DATE ACCEPTED	DX	Ht.	Wt. lbs.	CMV

Blood Group B ORG	Patient Name	Sta.	AGE	DATE ACCEPTED	DX	Ht.	Wt. (lbs.)	CMV

Obliterans

+ cross match needed

previous T *Domino heart donor

Removed from list:
Ramer, K BL 5/30/03

Date: 6/20/03
To: Transplant Team
From:

HEART/LUNG AND LUNG TRANSPLANT CANDIDATES

ACTIVE

Blood Group A ORGAN Patient Name	Sta	AGE	DATE ACCEPTED	DX	Ht.	Wt. (lbs.)	CMV
BL		20	5/9/2003	Cystic Fibrosis	5' 1"	101	Pos.

Blood Group AB ORGAN Patient Name	Sta	AGE	DATE ACCEPTED	DX	Ht.	Wt. lbs.	CMV

Blood Group B ORGAN Patient Name	Sta.	AGE	DATE ACCEPTED	DX	Ht.	Wt. (lbs.)	CMV

+ cross match needed

previous T *Domino heart donor

Removed from list:

FAX COVER SHEET

USE THIS COVER SHEET WHEN FAXING DOCUMENTS CONTAINING PROTECTED HEALTH INFORMATION. OBTAIN PATIENT AUTHORIZATION WHEN NECESSARY.

RECIPIENT'S INFORMATION	
Name: URGENT to Jim Creger	Date: February 13, 2004
Facility: UNOS Organ Center	Time:
Fax Number: 804-697-4372	Telephone Number:
SENDER'S INFORMATION	
Name:	Telephone Number:
Facility: Heart-Lung and Lung Transplant Program	Fax Number:
Address: Dept. of CT Surgery,	No. of Pages (including cover page): 9
Verification Checklist: ☐ Fax number pre-programmed (no further validation required) ☐ Validate requestor ☐ Confirm receipt faxed information	Information Faxed (do not write protected health information in this section): **Jim-Per our discussion yesterday. Here is all the information to have our candidate's time reinstated. from endorsed the replacement of the time. Please reinstate the time as soon as possible. This woman has a real possibility of being bypassed for her lung transplant. Please call me when you have replaced this time. Thank you for your help, RN, MS**

**** CONFIDENTIALITY NOTICE ****

This fax communication and any attachments may contain confidential information for the use of the designated recipients named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this fax in error, please notify the sender immediately by calling the phone number above to arrange for destruction of these documents.

Thank you.

4/8/03

February 11, 2004

UNOS Organ Center
Fax: 804-697-4372

RE:
HIC #

To Whom It May Concern:

We are writing to request the replacement of waiting time for candidate in June, 2003 Ms. [redacted] requested to go on hold for a vacation from June 7, 2003 until June 19, 2003. During that time she was placed on hold on the UNOS list and on our internal [redacted] list. On June 20, 2003 Ms. [redacted] was contacted by [redacted], RN, MS to confirm her desire to return to the transplant list. On June 20, 2003 Ms. [redacted] was returned to active status on the internal transplant list. Both the internal transplant list and the selection committee agenda for the following weeks meeting reflect the active status for this candidate. Due to unknown circumstances, Ms. [redacted]'s status was not changed on the UNOS list. This error was sadly unobserved until February 4, 2004 when she was returned immediately to active status on the UNOS computer. Our program is requesting the return of time missed (6/20/03-2/4/04) while this candidate was incorrectly status 7 on the UNOS computer.

Corrective action has been taken to prevent any future occurrence of this problem. The following practices have been instituted:

1. A program UNOS "candidate waiting list" will be printed weekly and reconciled with the internal transplant list by the program administrator.

2. A printed copy of each candidate's UNOS "Status History" will be printed at the time of listing and any time a modification is performed. This printed copy will reside in each patient's chart in a central location known to all using the chart. It will be consulted by the physicians seeing the candidate in transplant clinic every 3-4 months.

Fortunately, it appears [redacted] was not bypassed for a transplant during this time frame. Thank you for your consideration of this issue and it is hoped the time may be replaced in an expeditious manner.

Sincerely

[redacted]

[redacted], M.D.
Director
Heart-Lung and Lung Transplant Program

February 11, 2004

[redacted] Lung Transplant Program
C/O [redacted] RN, MS
Fax: [redacted]

Re: Approval for reinstatement of UNOS listing time

Dear Lung Transplant Team:

Pursuant to UNOS policy we are required to notify you of a request to reinstate listing time for a candidate on our list. Attached you will find a "Waiting Time Modification Form" and a letter detailing the error in not reactivating our patient. We are required to obtain your approval for this reinstatement. Please sign the consent below and return this letter to our program so we may submit the materials to UNOS.

Thank you very much,

[redacted], M.D.
Director
Heart-Lung and Lung Transplant Program
[redacted]

As a [redacted] Lung Transplant Program UNOS representative, I approve of the reinstatement of [redacted] Medical Center ([redacted]) candidate [redacted]'s UNOS waiting time for the period of 6/20/03 until 2/4/04.

[redacted]

UNOS Representative Name

UNOS Representative Signature and Date

Adjust Waiting Time for Lung Candidate

Successfully adjusted waiting time

Back Update

Provider Information

Transplant Center: [redacted]
24 Hour Contact Phone Number: [redacted]

Requested By:

Demographic Information for Candidate SSN: [redacted]

Name: [redacted]
DOB: 10/17/1982

List Date: 05/09/2003 13:22:36
Gender: F

Previous UNOS Waiting Time By Status (Days Hrs:Min:Sec)

Status	Accumulated Time	Adjustment	Adjusted Accumulated Time
0 - Active	28 days 1:21:22	229 days 0:0:0	257 days 1:21:22
7 - Temporarily Inactive	243 days 3:12:3	0 days 0:0:0	243 days 3:12:3

Inactive Lung Program Penalty Time History for [redacted]

Inactive Date	Penalty Date	Reactivate Date	Inactive Penalty Days
No Inactive Penalty Time Found			

Lung Waiting Time Information

Status to Adjust:
Amount of Time to Adjust: Days Hours Minutes
Is this a Backdate? Yes No
If not backdating, then select one of the candidate's previous statuses:

Back Update

Public Burden/Privacy Act Statements