

OPTN/UNOS Data Advisory Committee Summary

I Organ Availability Issues:

Action Items for Board Consideration:

- None

Other Significant Items:

- None

II Patient Access Issues:

Action Items for Board Consideration:

- None

Other Significant Items:

- None

III Other Issues:

Action Items for Board Consideration:

- The Board is asked to approve the recommendation that the pilot study of collection of SF 36 data, as outlined in the Data Working Group's proposal, be carried out for kidney, pancreas, heart, lung, and liver patients and recipients (Item 1, page 3).
- The Board is asked to approve modifications to Policy 7.4.1, which addresses notification of the recipient's death or graft failure (Item 4, page 5).
- The Board is asked to approve modifications to Policy 7.6.2.1, which addresses the time period for transplant centers to verify the refusal reason entered by the OPO (Item 5, page 5).
- The Board is asked to approve modifications to Policy 7.7 (Submission of Death Notification) and Policy 7.8.1, which addresses data submission standards (Item 6, page 6).
- The Board is asked to approve the recommendation that post transplant tumor data continue to be collected by the OPTN, and that the OPTN should take steps to facilitate complete and accurate collection of these data (Item 7, page 7).

Other Significant Items:

- The Committee formed a "best practices" subcommittee to study of the factors involved in the most complete, timely, and accurate submission of data. The Committee is interested in exploring the possibility collecting less data and at less frequent intervals on recipients after 10 years, and approved the following resolution, and requested that the OPTN/SRTR Data Working Group determine what are the key TRF data elements that need to be collected after 10 years follow-up, and at what time intervals the data should be collected (Item 3, page 4).

**REPORT OF THE
OPTN/UNOS DATA ADVISORY COMMITTEE
TO THE
BOARD OF DIRECTORS**

Minneapolis, MN
June 24-25, 2004

John M. Rabkin, M.D., Chair
Sandy Feng, M.D., Ph.D., Vice Chair

1. Update from the OPTN/SRTR Data Working Group (DWG). Dr. Larry Hunsicker, Chair of the DWG presented the following DWG proposal to study multiple transplant outcomes:

Rationale for a New Approach to Analysis of Transplant Outcomes

Essentially from the beginning, analysis of transplant outcomes has focused on time to death and time to graft loss. While these are clearly important outcomes, with improved patient and graft survival rates, they are no longer the only relevant outcomes to consider. The ACOT has recommended that the OPTN begin to collect and analyze information on the impact of transplantation on “quality of life.”

Limitations of the Exclusive Focus on Death and Graft Failure

In deceased donor kidney allocation, substantial priority is assigned to children based on the impact of transplantation on intellectual, physical, and social maturation. It is striking that there are no OPTN data dealing with the impact of early transplantation on these outcomes. More broadly, in children life expectancy following transplant is typically long, so that it is hard to get good data on the impact of transplantation on survival. In liver transplantation, the current MELD/PELD system assigns low scores to patients with cholestatic disease. These patients may not die quickly, but some have argued that they may be very sick for a long time. Similarly, with lung transplantation, the proposed new allocation system will give lower priority to patients with COPD relative to those with pulmonary hypertension, who die faster. But the COPD patients may have similar or worse disability.

Statistical Advantages to Broadening Examined Endpoints

There is a strong likelihood that alternative outcomes such as morbidity and functional status will be highly correlated with mortality risk. But mortality (or graft failure) data can be observed only once per patient (or graft), and then “too late.” Cumulative morbidity and functional status can be measured on many occasions and may offer greater statistical power in analyses. Time-series analyses on non-terminal outcomes may permit early intervention on high risk patients.

Proposed Domains (Dimensions) of Transplant Outcomes

Mortality.

Cumulative Morbidity: Adverse medical events, including graft loss and other events, primarily evidenced at least initially by hospitalizations.

Functional Status: Ability to perform functions required/desired in daily life.

Psychological Distress: Depression, anxiety, etc.

Resource Use: Effort/resources needed to care for the patient, again focusing initially on hospitalization.

The Importance of Both Pre- and Post- Transplant Data

At least one definition of “the expected benefit of transplantation” is “the difference between the expected outcomes if a transplant is performed and the expected outcomes if a transplant is NOT performed, as estimated at the time of a potential organ offer.” To estimate this benefit, we need to have information about the expected outcomes both of those transplanted, and those selected for transplant but still waiting.

Current and Proposed Data Sources for the Five Dimensions

Mortality: Now captured by the OPTN/UNOS system, and supplemented by death data from the Social Security Death Master File or National Death Index.

Morbidity: Limited hospitalization data is now collected on transplant recipients. The new forms will ask post-transplant patients about *all* hospitalizations since last reports. OPTN/UNOS collects no data about

waiting-list patient hospitalizations. CMS collects complete data on kidney candidates and recipients who have Medicare primary coverage. We have obtained consent from Pennsylvania and Virginia to get comprehensive hospitalization data on transplant candidates and recipients from those states (as a starter). *Disability/Functional Status:* OPTN/UNOS collects functional status information on transplant recipients at transplant and on follow-up forms, but on transplant candidates only at the time of registration. While these data correlate with outcomes, the grading is not sufficiently granular to capture less than gross loss of function. We propose to capture this information in our pilot using the SF36 physical scale and replacing the current UNOS functional scale with the Karnofsky Index. The Karnofsky Index has 10 levels of function spread from minor impairments that do not adversely affect function to a moribund state. It is the standard, best validated objective scale for functional status. It can be completed at the time of patient clinic visits in less than one minute.

Psychological Distress: No data collected currently by OPTN/UNOS. We propose to collect this information from the SF36 mental scale.

Resource Use: OPTN/UNOS currently collects no data on this subject, although the NOTA mandates the reporting of comparative costs of transplantation. We propose to estimate effort needed to care for the patient at least initially from hospitalization data, using uniform coding based on the DRGs weights and length of stay.

Relation of the Proposed Analysis to OPTN/UNOS Policy Formulation

There is no intent for the proposed analyses to force any particular approach to the formulation of deceased donor organ allocation or other OPTN/UNOS policy. The proposed approach to analysis will simply inform OPTN/UNOS committees more broadly about the outcomes of transplantation. The Board and the Committees will remain free to use the information as they find appropriate, considering the multitude of different considerations.

Three Approaches to Analysis of Alternative Endpoints

1. Each endpoint can be analyzed separately, using traditional methods. But this approach does not facilitate study of the mutual correlations and trade-offs among the outcomes.
2. The impact of morbidity, functional status, and the like can be integrated with survival, using a “quality adjusted life years” approach (QALY). But the weighting given to the various outcomes is both rather arbitrary and very variable among individuals.
3. The multiple outcomes can be studied in a model with a multivariate outcome. That is, outcomes in all the different dimensions can be considered as a single vector (per individual). In this approach the mutual correlations among the outcomes are observed directly (as the covariance matrix) in the analysis. This approach is objective, and leaves the weighting of the components (if needed) to the policy makers and individual physicians/patients. The observation of negative correlations can elucidate trade-offs in therapeutic decisions.

Methods for Combined Analysis of Multiple Outcomes

Analysis of a multivariate outcome (multiple outcomes in a single model) is a statistically innovative and challenging approach, particularly when the outcomes are scaled differently. We assume that different groups (SRTR, OPTN, HHS, other interested investigators) may want to work out different methods, and we encourage this. The final approach chosen by different analysts may differ because they have different goals:

- Optimize use of limited resources (organs or costs)
- Optimize outcomes for a particular patient.

What kinds of questions could be answered?

Benefit: What is the outcome for the average patient with and without transplant?

Policy: How would outcomes be changed by policy changes?

Subgroups: What are the differences among patient subgroups?

Individuals within subgroups: How much variation is there among individuals?

Correlation: Are the individuals who are at high risk for one outcome also at high risk for other outcomes?

An Important Distinction

Formulation of public policy such as for allocation of deceased donor organs (by type), requires choice (by the policy makers) of a single final metric based on weighting of one or more of the outcomes. i.e., the *offer* of an organ must be objective. But the decision of a patient and his/her doctor to *accept* an organ may be

based on each individual's weighting of the outcomes. Reporting the multivariate outcome (rather than using a common weighting such as a QALY) permits each individual to bring his/her own preferences to the decision.

Pilot Methods

Patients will be selected using random sampling from OPTN/UNOS patients (over sampling for specific populations). The transplant centers will be contacted to get addresses and alert them of the study. All forms will be mailed by and returned to UNOS. Letters will include appropriate consent forms. Patients not returning forms will be recontacted by mail and by phone in staged strategy to maximize returns.

Specific Recommendations of the DWG to the Data Advisory Committee.

1. Replace the present functional status scale on the current data collection forms with the Karnofsky Index. We have been assured that this would require only substitution of the Karnofsky functional levels for those on the current pick list. That is, this change would not require any action by OMB and could be implemented at any time.
2. Consider the DWG proposed pilot study of collection of SF36 data. Study to be done by OPTN/UNOS as part of contract for next budget cycle. Targeting 500 returns per group, we will send out 600 forms for adult (18 or older) patients:
 - Each organ transplant type (kidney, heart, lung, and liver)
 - Patients on waiting list (at listing and median time to transplant or six months, whichever is less)
 - Transplant recipients at time of transplant, 6 months, and one year.

We will also design a separate trial for children (< 18 years old) in cooperation with the Pediatric Committee.

Discussion followed the presentation by Dr. Hunsicker. Some of the issues raised by the Committee were: (1) Some committee members felt that the current method of collecting functional status, which is based on the NYHA scale and is widely used, is sufficient and the extra level of granularity in the Karnofsky Index was not necessary. (2) In addition to studying the four organ types presented by Dr. Hunsicker, the Committee wished to study pancreas, although acknowledging that the majority of patients and recipients would be kidney-pancreas transplant. Dr. Hunsicker agreed to this request. (3) Concern was expressed that to obtain 500 cases much more than 600 questionnaires would have to be sent out. (4) Concern was expressed about the completeness and accuracy of the data collected. (5) Concern was expressed about the potential that the transplant center may have to bear some of the costs, particularly in the collection of the Karnofsky Index. (6) Are there IRB and HIPAA issues?

After the discussion the Committee voted on the two recommendations from Dr. Hunsicker. The Committee approved the following resolution:

***** RESOLVED**, that the proposal that the Karnofsky Index replace the current method of collecting functional status on the current data collection forms be submitted for public comment in August 2004.

Committee vote: 15 For, 2 Against, 0 Abstentions

The Committee recommends that the Board approve the following resolution:

***** RESOLVED**, that the Board supports the pilot study to collect SF 36 data, as outlined in the Data Working Group's proposal set forth above for kidney, pancreas, heart, lung, and liver candidates and recipients, and directs the appropriate committee(s) to submit a detailed proposal to HRSA not later than September 30, 2004.

Committee vote: 17 For, 0 Against, 0 Abstentions

2. Disposition of Recommendations from the DWG Regarding Modifications to the OPTN Data Collection Worksheets. The OPTN and SRTR contracts, effective in September 2000, tasked the OPTN/SRTR Data Working Group and the Data Advisory Committee with minimizing any undue burden of reporting while improving data efficiency, measurement of intermediate transplant endpoints, and measurement of resource utilization. This effort focused chiefly on specific electronic forms within the TIEDI® (Transplant Information Electronic Data Interchange) components of the data collection system: organ-specific

Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms; the Cadaver Donor Registration (CDR) for (since renamed the Deceased Donor Registration (DDR)); Donor Histocompatibility (DH) and Recipient Histocompatibility (RH) forms; and the Post Transplant Malignancy form. In order to identify the smallest set of data variables that the OPTN must collect, the DWG recruited five workgroups, each with Chair-appointed representatives of the Liver/Intestine, Kidney/Pancreas, Thoracic, Histocompatibility, and Organ Procurement Organization (OPO) Committees; representatives of the Scientific Registry of Transplant Recipients (SRTR); and UNOS staff. During the Spring of 2002, the DWG reviewed the work of each group and approved a set of organ- and form-specific recommendations for DAC consideration. The Committee supported most of the DWG recommendations but, for some elements, made modifications or additional recommendations. Additional development continued through the end of 2002, with further recommendations from the DWG's September 17 meeting and the DAC's October meeting. In January 2003, the Committee held a conference call to finalize the recommendations for inclusion in five sets of proposals that were submitted for public comment in March, 2003. In addition to recommendations of the DWG, these proposals included specific recommendations of the Organ Availability and Ad Hoc International Relations Committees. At its May meeting, the Committee reviewed all public comments, as well as a small number of final recommendations by the Data Working Group, and made final revisions to the four TIEDI@ proposals. The OPTN/UNOS Board of Directors approved the DAC's final recommendations in June 2003. During the subsequent four-month internal UNOS operations process, specific staff refinements were necessitated by UNetsm formatting requirements for consistency and system integrity reasons. Lastly, the newly proposed data collection instruments were compiled into a comprehensive submission package for the review of the Office of Management and Budget (OMB).

3. **Best Practices Subcommittee Report.** At its September 2003 meeting, the Committee voted unanimously to pursue a "best practices" study of the factors involved in the most complete, timely, and accurate submission of data. The Best Practices Subcommittee met by teleconference on April 30, 2004. In attendance were Marian O'Rourke and Emily Johnson. Erick Edwards, Alan Ting, and Christine Tolleris from UNOS also participated in the call. Marian O'Rourke reported the main discussion points from the call, and these were discussed by the full Committee:
- The OPTN Charter & Bylaws were implemented on May 1, 2004. Bylaw 2.08(2a-d) addresses action that could be taken if transplant centers, OPO's and histocompatibility laboratories fail to submit data within time periods as may be specified in the OPTN policies. Because of this, data submission completeness, *per se*, may now not be an issue.
 - Data completeness and data accuracy are two separate issues. A center/OPO/laboratory could be fully compliant with data submission completeness, but the data may not necessarily be accurate.
 - The new data collection worksheets will be implemented in the Summer of 2004 after OMB clearance. These revised forms are intended to ease the burden of data collection. A suggestion was made to examine the proportion of recipients listed as "lost to follow-up", over time, to determine if compliance is improved with the new forms.
 - The Transplant Administrators Committee uses UNetsm to collect information about the number of staff hours each center use to collect and input data into the UNOS computer.
 - Some barriers to sending complete and accurate data are:
 - The transplant centers do not necessarily follow patients "for life." The recipient may not go back to their transplant center for follow-up because of insurance and/or nephrologist issues.
 - There is no financial incentive to complete forms.
 - Insufficient staff.
 - Should the DAC examine the practices of the top and bottom 5% of centers in terms of compliance and accuracy of data submission?
 - The UNOS Policy Compliance Department monitors data submission compliance. 18 transplant centers and one histocompatibility laboratory will be referred to the Membership and Professional Standards Committee at its May 2004 meeting.
 - The center-specific report is published on the web and updated semi-annually. Centers are sensitive to the proportion of "lost to follow-up" reported by their center. Furthermore, insurance companies may also be interested in these numbers. There may be some incentive to keep the proportion of reported "lost to follow-up" low.
 - Do we have to collect follow-up data indefinitely? If so, should the time intervals between collection be increased (currently it is 1 year) after a certain time, e.g., after 10 years. Furthermore, should all data on the

current follow-up forms be collected indefinitely, or could the data collected be limited? An “active” approach may be more successful for these long term recipients. For example, at periodic intervals, UNOS could generate a list of these patients for each center and ask if the recipient is still alive.

The Committee is interested in exploring the possibility collecting less data and at less frequent intervals on recipients after 10 years post-transplant, and approved the following resolution:

***** RESOLVED**, that the Data Working Group (DWG) shall determine what are the key TRF data elements that need to be collected after 10 years follow-up, and at what time intervals the data should be collected. The DWG should determine who uses (and/or will use) this data (e.g., CMS, OPTN, SRTR) and for what purpose(s).

Committee vote: 17 For, 0 Against, 0 Abstentions

Marian O’Rourke agreed to be the chair of the Best Practices Subcommittee.

4. **Proposed Modifications to Policy 7.4.1.** The Committee noted that transplant centers were not always notified immediately of a patient’s death or graft failure, particularly if the patient is in the care of a physician or institution outside the transplant center. In these cases, it was sometimes difficult to comply with Policy 7.4.1. Therefore, the Committee recommends that the Board approve the following resolution:

***** RESOLVED**, that the following modifications to Policy 7.4.1 shall be approved, and implemented on June 25, 2004.

7.4 SUBMISSION OF ORGAN-SPECIFIC TRANSPLANT RECIPIENT FOLLOW-UP FORMS

- 7.4.1 The appropriate Transplant Recipient Follow-up form must be submitted to UNOS within 14 days of notification of the recipient’s death or graft failure.**

Committee vote: 17 For, 0 Against, 0 Abstentions

5. **Proposed Modifications to Policy 7.6.2.1.** The Committee noted that the current policy states that “If, after 15 days following the recording of the offer by the OPO, the transplant center fails to verify the refusal reason as entered by the OPO or fails to enter a different refusal reason, the refusal reason as entered by the OPO will be considered accurate and validated.” Concern was expressed that the transplant center did not necessarily know when the OPO entered the refusal reason, and that the center would have to constantly monitor UNetsm to determine when the OPO enters the refusal code. In order to simplify the procedure for transplant centers the Committee voted to recommend to the Board the following resolution:

***** RESOLVED**, that the following modifications to Policy 7.6.2.1 shall be approved, and implemented on June 25, 2004.

- 7.6.2 Recording and Reporting of the Outcomes of Organ Offers. Recording and reporting of the refusal reasons must be a cooperative effort between the OPO and the transplant center.**

- 7.6.2.1 The OPO and transplant centers should be familiar with the current refusal reasons and, to the extent possible, should refer to these reasons explicitly during the offer/refusal transaction. ~~If, after 15 days following the recording of the offer by the OPO~~ 45 days following the date of the match run from which the offer was made, the transplant center fails to verify the refusal reason as entered by the OPO or fails to enter a different refusal reason, the refusal reason as entered by the OPO will be considered accurate and validated. The OPO and the transplant center should make every reasonable attempt to resolve conflicts in recorded refusal reasons. However, in the event of a dispute between the OPO and the transplant center regarding a recorded reason for refusal, the record of the transplant center will take precedence for the purposes of reporting by UNOS.**

Committee vote: 17 For, 0 Against, 0 Abstentions

6. Proposed Modifications to Policy 7.7 (Submission of Death Notification Information) and Policy 7.8.1. Currently, OPTN/UNOS Policy 7.7 states that monthly death notification information must be submitted for each donor hospital by the OPO before the close of the subsequent calendar month. OPTN/UNOS Policy 7.8.1 states that donor referral information must be 95 percent complete within three months of the expected due date and 100 percent complete within six months of the expected due dates. Previously, Policy 7.7 referred to the submission of donor referral information. At the June 2003 meeting of the OPTN/UNOS Board of Directors, the Board approved a modification to Policy 7.7 that now refers to the submission of death notifications. The Association of Organ Procurement Organizations (AOPO) Quality Improvement Council, the OPTN/UNOS OPO Committee and the OPTN/UNOS Data Advisory Committee made the request to modify the policy in an effort to clarify the definition of hospital referral data. The name of this data was changed from "Donor Referrals" to "Death Notifications."

Prior to the modification of Policy 7.7, the Division of Transplantation (DoT) identified an issue with the submission of the data. OPOs were non-compliant submitting the data every month. Under the old Donor Referral Policy 7.7, OPOs needed to submit the data within thirty days of the referral call. Under the modified Death Notification Policy 7.7, OPOs have until the end of the subsequent calendar month to submit the data. Policy 7.8.1 establishes compliance thresholds in which OPOs are required to follow when submitting donor referral data. The submission of death notifications should reflect one clear expectation for data compliance, and therefore Policies 7.7 and 7.8.1 should be modified accordingly.

The Committee recommends that the Board approve the following resolution:

***** RESOLVED, that the following modifications to Policy 7.7 (Submission of Death Notification Information) and Policy 7.8.1 shall be approved, and implemented effective June 25, 2004.**

7.7 Submission of Death Notifications

All monthly death notification information must be submitted by the OPO for each donor hospital ~~by the OPO~~ before the close of the subsequent calendar month.

7.8 Data Submission Standards

7.8.1 Each OPO, Transplant Center and Histocompatibility Laboratory must meet the following standard for submission of data collected on all forms ~~and donor referral information~~ to the UNOS Transplant Registries: 95% of expected forms complete within three months of the due date and 100% of expected forms complete within six months of the due date. 100% of the potential recipient refusal code data must be submitted within 30 days of the match run date.

Committee vote: 17 For, 0 Against, 0 Abstentions

7. Data Submission to the Post-Transplant Tumor Registry. Some concern has been expressed about the lack of completeness of the data collected on the Post Transplant Malignancies Worksheets. Dr. Myron Kauffman briefed the Committee on the history of the Post-Transplant Tumor Registry, and outlined the concerns expressed about the lack of completeness of data collection. In 1998, UNOS obtained two one-year Cancer Control Grants from the American Cancer Society to incorporate the existing Cincinnati Transplant Tumor Registry into an electronic format to be managed by UNOS. A Transplant Tumor Advisory Committee was formed to construct four separate tumor forms that would be utilized to collect more detailed transplant tumor data. The four forms were: Donor Related Malignancies, Recurrence of Pre-transplant Malignancy, Post-transplant Solid Malignancies, and Post-transplant Lymphoproliferative Disorder (PTLD). As a result of the above activities UNOS Contract with Health Resources and Services Administration (HRSA) was amended and supplemented to include funds for the construction of a prospective transplant tumor registry as an integral portion of the OPTN Database. The Transplant Tumor Registry of the OPTN Database became operational on January 1, 1999.

The current concerns about the completeness of data collection are primarily based on The Scientific Registry of Transplant Recipients (SRTR) preliminary data on the linkage of OPTN tumor data with that of the Detroit Metropolitan National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) which was reported at the conference call meeting of the Post-Transplant Tumor Technical Advisory Committee (PTTRTAC) on August 29, 2002, that indicated there was substantial underreporting of malignancies to the OPTN. The actual number of cases was 40 for the period from 1990 through 1999.

Since the OPTN started collecting limited post-transplant data on March 3, 1997, it was inappropriate to compare SEER data with OPTN data for the period of 1990 through 1996. In the three years (1997-1999) there were 14 cases reported to SEER that were not reported to the OPTN. An important next step in the evaluation of potential underreporting is to capture information on the 14 cases reported to SEER and not captured by the OPTN to assess potential reasons for underreporting to the OPTN and, to understand the possible cause(s) of the underreporting. One possible reason for underreporting includes lack of information regarding the cancer by the transplant reporting team. Further, since the transplant patient may travel significant distances for their treatment it is possible that the underreporting rate may be underestimated. If the catchment area for the SEER data is the Detroit Metropolitan area, or all of Michigan, but patients are being referred from non-contiguous states, cancer cases diagnosed elsewhere may be missed.

The SRTR subsequently reported data obtained from the SEER Registry in Seattle and stated that there were 301 cases from SEER and only 83 (28%) from the OPTN. The SEER Registry reported 57 tumors for the years 1999-2000, during which time there were 796 first transplant recipients, or 866 first and repeat transplant recipients (excluding multiorgan), who resided in Washington state at the time of listing, for a tumor incidence of 7.2% or 6.6%, with an estimated average follow-up time of about 2-3 years. If we included multiorgan transplants, there were 802 first transplant recipients, or 873 first and repeat transplant recipients, for a tumor incidence of 7.1% or 6.5%. This extraordinary tumor incidence merits further investigation. The results of the SEER linkage exercise suggest that more effective methods of cancer surveillance need to be developed by the OPTN. However, in order to accomplish this, a more complete understanding and characterization of missing data need to be achieved. UNOS has recently compiled the number and percentage of non-skin, non-lymphoid, *de novo* solid tumors in deceased and living donor transplants for kidney, heart and liver, by individual transplant centers, for the years 1999-2000. The follow-up time of these patients is approximately 2-3 years. During this period of time, the incidence of post-transplant *de novo* tumors was 1.2% for kidney, 1.6% for liver, and 3.1% for heart. From looking at individual center data, it appears as if some major centers are not reporting or are substantially underreporting post-transplant malignancies. UNOS is currently investigating why centers with large volume of transplants have not reported any cancer, why discrepancies in reporting post-transplant malignancies exist among centers, and how mechanisms of reporting post-transplant malignancies differ among transplant centers.

The utility of the tumor data is obvious, and therefore, it is essential to develop a better understanding of any biases or underreporting of cancer in this high-risk population. As a result of the preliminary data provided by the SRTR on underreporting of cases, we need to explore further the level and bias in underreporting of cancers for different transplanted organs and for different groups of transplant recipients. Knowing where additional cancer cases, problems and biases are would help UNOS improve and redirect its effort in cancer ascertainment.

On March 19, 2004, a letter signed by Dr. John Rabkin and Dr. Myron Kauffman was sent to all transplant program directors showing their statistics for the total number of transplants during 1999-2000 and the number and percentage of those recipients with any report of post transplant *de novo* solid tumors, non-melanoma skin cancers, or post transplant lymphoproliferative disease (PTLD). The letter also emphasized the importance of collecting complete and accurate data and asked their assistance in this matter.

Possible methods to increase the completeness and accuracy of the data were discussed by the committee. These include linking to external databases such as the SSDMF and the USRDS. Dr. Dreis said that his department is working with the National Cancer Institute, which oversees the SEER Registries, to see if it can link with the OPTN database. Another suggestion was to use a tiered approach to collect data, i.e., collect basic information, and then more detailed information. The Post Transplant Malignancies Worksheets had recently undergone revisions to make them more "user-friendly," and in addition, certain data elements that were difficult to collect have been eliminated. The Committee also discussed the importance of collecting the data, and requested that UNOS staff develop a letter that describes the OPTN and its need for this data. The letter would be sent to transplant center staff asking them to share it with relevant physician offices (e.g., oncologists), institutional cancer registries, and medical record departments.

The Committee supports continued collection of the data, rather than abandoning the database, and recommends the following resolution for consideration by the Board:

***** RESOLVED, that post transplant tumor data continue to be collected by the OPTN, and that the OPTN should take steps to facilitate complete and accurate collection of these data.**

Committee vote: 16 For, 0 Against, 0 Abstentions

8. Data Release Policies. At the previous DAC meeting in September 2003, a proposal was made to consider whether or not Policies 9.0 (Release of Information to the Public) and Policy 10.0 (Access to Data) should be combined and some perceived redundancies removed. After further discussion at this meeting, the Committee decided that the two policies do not need to be merged, as they addressed different topics. Policy 9.0 primarily deals with release of aggregate data, and Policy 10.0 with raw data for analyses and projects.
9. Proposed Lung Allocation Policy. This proposal was submitted for public comment on March 25, 2004. The Committee will have an opportunity to comment on the data elements that will be collected from candidates prior to listing once they have been decided by the Thoracic Organ Transplantation Committee.
10. Request from the OPTN/UNOS Pediatric Committee to Collect Pediatric Co-Morbidity Data. Dr. Mike Ishitani stated that he (as a representative of the DAC) had worked with the Pediatric Committee to come up with co-morbidity data for the Transplant Candidate Registration form that were relevant to pediatric patients. He reported that the Pediatric Committee had approved these data elements and that they had been incorporated into the recommended forms changes. The DAC and the Pediatric Transplantation Committee now need to work on pediatric co-morbidity factors that should be collected on the Transplant Recipient Follow-up Forms. Dr. Ishitani felt that a joint DAC and Pediatric Committee Subcommittee should be formed to address this. The DAC members who volunteered to be on the Subcommittee were: Drs. Mike Ishitani, Sandy Feng, Edgar Milford, and Ms. Leslie Duncan. The DAC would write a letter to the Chair of the Pediatric Committee to request members from that committee.
11. SSDMF – An Update. Dr. Erick Edwards provided the Committee with an update.
 - As of April 16, 2004, 2577 registrations on the OPTN waiting list have been matched to the Social Security Death Master File (SSDMF).
 - Members have removed about 70% of the 2577 registrations for death.
 - About 4% have been removed for other reasons.
 - Of the 647 registrations yet to be removed by members, the majority are kidney (n=418), liver (n=128), and heart (n=64).
 - In only 6 registrations did a member provide a comment to disagree with the OPTN-SSDMF report.
 - Of 2465 transplant records linking to the SSDMF (data provided by the SRTR), 68% currently contain a patient status of "Dead" in the OPTN database.

OPTN/UNOS Data Advisory Committee
O'Hare Airport Hilton Hotel, Chicago, IL
May 3, 2004

Members Present

John M Rabkin, M.D.	Chair
Sandy Feng, M.D., Ph.D.	Vice Chair
Edgar Milford, M.D.	Region 1
Emily Johnson	Region 2
H Gareth Tobler, M.D.	Region 3
Leslie Duncan RN, MSN	Region 4
Brian Gallay, M.D., Ph.D.	Region 5
Chris S Kuhr, M.D.	Region 6
Michael B Ishitani, M.D.	Region 7
Chris Bryan, Ph.D.	Region 8
Edward Specht	Region 9
Pamela Kimball, Ph.D.	Region 11 (by teleconference)
Eugene Osborne	At Large
Flora Solarz, MPS	At Large
John St. John	At Large
Jim McCabe, MS, CPTC	At Large
David Gjertson, Ph.D.	At Large
Marian O'Rourke, RN	At Large

Members Unable to Attend

A. Joseph Tector, M.D.	Region 10
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Ex Officio Representatives

Charles F Shield, M.D.	Board of Directors
Michael Dreis, Pharm.D.	HRSA
Robert A Wolfe, Ph.D.	SRTR

Guest

Larry Hunsicker, M.D.	Chair, Data Working Group
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UNOS Staff

Alan Ting, Ph.D.	Liaison, Research
Erick Edwards, Ph.D.	Research
Berkeley Keck, RN	Information Technology
Christine Tolleris, MPA	Research
Myron Kauffman, M.D.	Research
Shawn Wray	Policy Compliance