

OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
June 26, 2007
SUMMARY

I. Action Items for Board Consideration:

- The Board of Directors is asked to approve two new hospital based histocompatibility laboratories. (Item 1, Page 5).
- The Board of Directors is asked to approve for designated program status four new programs in an existing member centers. The Board is also asked to approve one liver transplant program to perform liver donor transplants. (Item 1, Page 5).
- The Board of Directors is asked to approve two new non-institutional memberships and to continue membership for three organization members. (Item 1, Page5).
- The Board of Directors is asked to grant full approval to one liver program that performs live donor liver transplants. (Item 1, Page 5).

II. Other Significant Items:

- Annual Committee Goals: During its May meeting, the Committee was presented with the Goals that had been approved for the year and the progress that had been made on each. (Item 2, Pages 5-6).
- Update on the Efforts of the Joint Work Group for MPSC Process Improvement. The Committee was updated on the reports and actions that took place during the March 2007 Board of Directors meeting. (Item 3, Pages 6- 7).
- Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Work Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance. (Item 4, Pages 7-8).
- Program Related Actions and Personnel Changes: The Committee reviewed 40 key personnel change applications during its May meeting. (Item 5, Pages 8-9).
- Due Process Proceedings and Presentations: The Committee conducted three interviews and held one informal discussion with member organizations. One transplant hospital made a special presentation before the Committee. (Items 6, Page 9).
- Update on enforcement of mandatory Donation after Cardiac Death (DCD) protocols, which address required Model Elements at all OPOs and transplant centers. The MPSC discussed the activities of the DCD Policy Enforcement Working Group and its efforts to develop a process for documenting and monitoring DCD protocols. (Item 8, Pages 9-10).

- Live Donor Program Requirements: The Committee discussed the requirements for programs that perform living donor transplants and provided guidance to the Living Donor Policy Work Group on the development of oversight requirements and the content of the live donor kidney program application. (Item 9, Pages 10-11).
- Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data). A Subcommittee of the MPSC initially reviewed two cases of a death of a live donor that occurred prior to the May meeting. They concluded that no further action was required as there was not any evidence of a policy violation and there was no evidence of patient safety issues at the centers. The Committee reviewed the findings of the Subcommittee during its May meeting and agreed that no further action was required on either case. (Item 10, Page 11).
- Pancreas Outcome Analysis Model: The Committee was updated on the ongoing issue of pancreas (including kidney/pancreas and pancreas after kidney) program outcome monitoring. The Committee agreed that the Pancreas Transplantation Committee needed to review the variables, including recipient and donor risk factors, before development of the model. The MPSC was informed that the Pancreas Transplantation Committee would be considering this issue during their next meeting on May 18, 2007. (Item 11, Pages 11-12).
- Number of days a program has its waitlist inactive (but not membership): Staff presented the Committee with an overview of the programs that had periods when the Waitlist Program Status field was set to temporarily inactive during 2006, but the program had not inactivated its membership status. The Committee agreed that further review of this data should be performed by the Data Subcommittee as part of its review of functionally inactive programs. (Item 12, Page 12).
- Proposal 2: Proposed Notice of Change to Policy 7.1.5 and Proposed Modifications to the Living Donor Registration and Living Donor Follow-Up Forms. The Committee reviewed this proposal and supported the concept but is making recommendations for further changes. (Item 13, Pages 12-14).
- Proposal 3: Proposed Modifications to Policy 7.3.3 “*Submission of Living Donor Death and Organ Failure Data*” sponsored by the (Living Donor Committee). The Committee reviewed this proposal and is recommending a modification to the proposal (Item 14, Pages 14-15).
- Proposal 4: Proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms. The Committee reviewed this proposal supports it as written. (Item 15, Page 15).
- Proposal 5: Proposed Modifications to Data Elements on UNetSM Deceased Donor Registration (DDR) Form. The Committee reviewed this proposal and supports it with amendments. (Item 16, Page 16).
- Proposal 7: Proposed Modifications to OPTN/UNOS Bylaws, Appendix A, Section 2.06A, (b), (3-7). The Committee reviewed this proposal and supports it as written. The Committee is asking the Patient Affairs Committee to consider developing language to address OPOs and histocompatibility laboratories. (Item 17, Page 17-18).

- UNOS Actions: During the May meeting, the Committee members agreed that actions regarding Bylaws and Policy, and program specific decisions made during the OPTN session would be accepted as UNOS actions. (Item 20, Page 19).

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**REPORT OF THE
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE
TO THE
BOARD OF DIRECTORS
St. Louis, MO
June 26, 2007**

**Timothy L. Pruett, M.D., Chair
Niloo M. Edwards, M.D., Vice Chair**

- I. Regular Committee Meetings. The following report presents the Membership and Professional Standards Committee's (MPSC) deliberations and recommendations on matters considered by the Committee during its May 1-2, 2007, meeting.
1. Membership Application Issues: The Committee recommends that the Board of Directors approve four new programs in existing member centers, and one liver program to perform live donor transplants.

In addition to considering applications for institutional membership, the Committee reviewed applications for continued medical/scientific and public organization membership, and applications for new Business and Individual Membership (two-year terms), and recommends that the Board of Directors approve these applications.

Reports from Conditionally Approved Programs: During its May 2007 meeting, the Committee approved a change in status of a liver program that performs live donor transplants from 12-month conditional approval to full approval. The program had previously been conditionally approved pending performance of seven live donor hepatectomies by the second primary surgeon.

The Committee reviewed and approved a yearly progress report from a lung transplant program whose primary physician was approved under the pediatric pathway with yearly reporting stipulations until the primary lung transplant physician criteria are fully met. The Committee also reviewed bimonthly progress reports for four transplant programs (1 kidney, 1 pancreas, and 2 heart programs) that are conditionally approved for 12 months to allow the primary physician to meet the full primary physician criteria or to allow the program to recruit a physician who fully meets primary physician criteria.

The Committee also reviewed the list of liver programs that had received conditional approval for the Live Donor Transplant component of their programs. The Committee noted that of the 14 programs that had received conditional status, five had not performed a live donor transplant since January 2006. All of the programs are being reminded that the Bylaws state that they "*must provide a report prior to the conclusion of the first year of conditional approval, which must document that the surgeon has met or is making sufficient progress to meet the objective of performing 7 live donor liver procedures or that the program is making sufficient progress in recruiting and bringing to the program a transplant surgeon who meets this criterion as well as all other criteria for a qualified live donor liver surgeon.*"

2. Overview of Annual Committee Goals: During its April meeting, the Committee reviewed the goals that had been approved for the year and the progress that had been made on each. A summary of the goals and the progress made on each is described below:

- Goal: Develop the process for action on referrals made to MPSC as a result of the new policy requiring notification of death or listing for transplant of a living donor.
Progress: Members were informed of the requirement and have begun to use the new online reporting option in the Patient Safety System that was activated on January 3, 2007.
- Goal: Partner with Living Donor Committee to determine what policies are needed to provide oversight of living donor programs (donor safety and patient outcomes).
Progress: A Work Group was formed and has been reviewing information distributed electronically. Members of the Work Group also met on April 16, 2007, by conference call to develop proposals for review by the full Committee. (See Section 4 of this report for additional details).
- Goal: Participate in the working group to be established by the OPO Committee to develop the required elements of the mandated DCD protocols.
Progress: MPSC members participated in the DCD Working Group developing protocol guidelines. The Board approved modifications to the Bylaws that establish model elements to be included in DCD protocols, during its December 2006 meeting.
- Goal: Consider any policy or procedures that need to be put in place to support violations of the newly passed policy that requires all DCD procurements to be done in accordance with an established protocol.
Progress: During the October Meeting of the MPSC, a DCD Policy Subcommittee was established and charged with developing policy and methods for monitoring and enforcing compliance as it pertains to the oversight of approved DCD protocols. The MPSC was given a progress report during its May meeting. (See Section 8 below for additional details).
- Goal: Continue work with SRTR to develop organ specific acceptance rate metrics of center performance.
Progress: The SRTR provided acceptance rate data factoring in a couple of newly identified variables. The MPSC Process Improvement Work Group 1 met by conference call on January 18, 2007, to discuss this issue and has recommended a pilot study through the Data Subcommittee. The MPSC was given a progress updated during its May meeting. (See Section 4 below for additional details).
- Goal: Provide a 6-month update to Board on progress or changes made in implementing the 2006 MPSC improvement project
Progress: A report was included in the March 2007 report to the Board of Directors as well as this document.
- Goal: Provide to the Finance Committee prior to the March 2007 Board meeting, an update on budgetary needs for next financial year.
Progress: Developed budgetary needs and presented them to the Finance Committee.

The Committee also discussed their work in terms of the HHS Program Goals and the Strategic Plan Goals. While the goals are not necessarily specific to the work of the Committee, it was agreed that it has a role with increasing DCD.

3. Update on the Efforts of the Joint Work Group for MPSC Process Improvement: During the November 2005 Board meeting, the Executive Committee and the Board of Directors directed the

Membership and Professional Services Committee (MPSC) to form a work group composed of members of the MPSC and the Board of Directors to identify improvements for, and propose changes to, the membership review processes and standards. This Work Group, in conjunction with the MPSC, has met now completed five of its six goals as outlined below.

The process improvement goals are listed below by their status:

Completed:

- The establishment of a confidential communication line directly to UNOS for individuals wishing to divulge sensitive information;
- Consideration of procedures that would improve the timeliness of required compliance with corrective action, site visit action plans, and MPSC review, along with requirements that failure of a center to meet timelines would prompt immediate consideration of adverse action; and the same would apply to instances of dishonesty in the provision of information or failure to adhere to representations in documents submitted;
- A Bylaw requiring members to notify the OPTN of reviews and adverse actions taken against them by other organizations.
- A Bylaw requirement specifically defining what constitutes onsite availability of transplant surgeon and physician coverage;
- Consideration of a bylaw that would prohibit a physician or surgeon who has been a primary focus in assessing activity leading to an adverse action which involves loss of membership of a program or a center to not be permitted to be primary physician or surgeon at another UNOS approved program;

Still under Development:

- Bylaws that enable the MPSC to determine how organ acceptance/turndown rates and deaths on the waiting list will be evaluated and incorporated into the standard elements of center performance in addition to patient and graft survival (work on this proposal continues in development and an update is provided in Item 4 below).

4. Offer/Organ Acceptance Rate Modeling: The Committee was updated on the Process Improvement Work Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used to evaluate program performance.

Background: The primary purpose of the metric is to identify programs that are inappropriately inactive and may pose a risk to patient safety. The Work Group agreed that each analysis will have to be organ specific to account for unique clinical and logistical characteristics, and requested that the Scientific Registry of Transplant Recipients (SRTR) create multi-variable models comparing actual to expected acceptance rates (looking at both offers and organs offered) for each organ starting with kidney, liver, and then the other organs.

Work Group 1, which was tasked with this effort, has met numerous times either in person or via conference call to review the proposed analysis models.

On January 31, 2007, Dr. David Mulligan updated the Committee on the Process Improvement Work Group's progress in the development of an agreeable methodology for collecting and analyzing organ acceptance/turndown rates and deaths on the waiting list, which can be used as a

flag to evaluate program performance.

A timeline was presented, which provided a chronology of the work beginning in January 2006 to this point. The “good organ” criterion was presented by Dr. Mulligan and SRTR staff. Good organ criteria are defined as kidney or livers transplanted within 50 offers and/or by one of the first 3 centers receiving an offer. The acceptance rate information for kidney and liver programs had been placed by SRTR on the programs’ private sites for review. A couple of criteria for data inclusion in the analysis were discussed between the Working Group and SRTR. The SRTR was scheduled to publicly release this center specific data to the public on January 11, 2007, when a decision was made by SRTR and HRSA to delay its release because some questions were raised regarding the data considered as good organ turndowns. The Committee members were apprised of a discussion regarding this issue that the Working Group had with the SRTR and its resulting decision to continue with piloting program reviews flagged with the current methodology for both kidney and liver. Dr. Mulligan explained the acceptance rate model has been developed with the knowledge that it is probably not perfect, but it is a tool that has identified four programs that subsequently closed, so it deserves a chance to be evaluated. Some discussion occurred regarding delaying any acceptance rate model until “better” turn down data is collected with DonorNet[®] 2007.

The Working Group expressed confidence in the current model so they were recommending that this spring, kidney and liver programs identified as having observed acceptance rates for both offers and organs below the expected levels with statistical significance, should be contacted and asked to provide information that will help the Working Group understand what this measure is actually determining. These programs will be told that this methodology is under testing and it is not being used as a performance determinant by the MPSC at this time. The Working Group will continue to report its findings at a future Committee meeting.

May Progress Report: During its May meeting, the Committee was updated on the development of the methodology. The SRTR paused in publicly releasing previously reviewed data in March, but recently provided the centers with newly calculated organ acceptance rate data for calendar year 2006 on the centers’ private websites. SRTR asked the centers to enter all their 2006 data by April 30, 2007. The SRTR will then continue to accept comments regarding the data’s validity and the appropriateness of the methodology used through June 15, 2007. It is expected that the final data will be published on the SRTR website by July 11, 2007. The SRTR has provided the Work Group with this data analyzed using the methodology developed previously. The Work Group is analyzing and discussing the results of the new dataset to determine if it is still feasible to pilot the review program for identified outlier kidney and liver programs. The Work Group plans to meet around mid-June 2007 to consider discuss these matters.

5. Program Related Actions and Personnel Changes: During its May meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status.

Additionally, the Committee reviewed 40 Key Personnel Changes and approved 36. Four applications for change in primary histocompatibility laboratory directors remain in process.

The Committee also reviewed a request by a Center to maintain an active heart/lung transplant program after voluntarily inactivating its heart transplant program. The Member requested that the program be allowed to remain active to allow for the ability to transplant two active patients waitlisted for a heart/lung transplant. The Member also requested that it be allowed to add future

heart/lung patients to the waitlist on a case-by-case basis with prior MPSC approval. After reviewing the Member's request, the MPSC approved the following resolution:

- ** RESOLVED, that the Bylaws Appendix B, Attachment I, XIII, C, (9) does not permit the Center to maintain an active heart/lung transplant program without active and approved heart and lung transplant programs.
- ** FURTHER RESOLVED, that the Committee recommends that the Center may maintain an active heart/lung transplant program by choosing to reactivate its heart transplant program. Should the Center choose to keep its heart transplant program voluntarily inactivated, the Committee recommends that the Center also voluntarily inactivate its heart/lung transplant program and transfer all waitlisted heart/lung patients to active centers.
- ** FURTHER RESOLVED, that the Committee may consider recommending to the Board of Directors that this Center be made a "Member Not in Good Standing" pursuant to the Bylaws, Appendix A, 2.06A(4) if the Center performs a heart/lung transplant while the heart transplant program is voluntarily inactivated.

The Committee voted 14 For, 0 Against, 2 Abstentions.

6. Due Process Proceedings and Informal Discussions: The Committee conducted three interviews and held one informal discussion with member organizations. .
7. Special Presentations: Representatives from a member center that operates a stand-alone non-renal transplant program, made a presentation to the Committee describing the development of the transplant program's infrastructure and support services. They also discussed the challenge of starting a new transplant center that is not associated with a renal transplant program. No action was required or taken by the Committee.

The Committee thought that this presentation was helpful to its ongoing discussion regarding the current Bylaws that address support services and program infrastructure.

8. Update on the Inclusion of Donation after Cardiac Death (DCD) protocols in Transplant Center Membership (OPO Committee): The Committee continued its discussion regarding requirements for DCD protocols as a condition of transplant center and Organ Procurement Organization (OPO) membership.

Background: This issue was first discussed by the Committee during its February 2006, meeting and it has continued to participate through the its' representatives in the efforts of the DCD Working Group. During the October 2006, meeting of the MPSC, a DCD Policy Subcommittee/working group was established and charged with developing policy as it pertains to the oversight of DCD protocols.

Update: The DCD model elements were presented to and approved by the Board in March 2007. The DCD policy notice with an effective date of July 1 was sent out on May 9, 2007. The model elements needed to be completed before the Work Group could move forward with developing enforcement criteria. The Board was also asked how the Work Group should handle enforcement when the institution indicates that it does not do DCD and would not have a DCD protocol. The Board took the position that they would like every transplant center and OPO to adopt and follow the model elements for a DCD protocol and not answer the question of what to do in cases where

the center/OPO did not adopt the required mandatory DCD protocol with model elements guidelines. The DCD Policy Work Group will be meeting on May 15, 2007, to continue its work.

9. Live Donor Program Requirements: During the October 2006 meeting, the Living Donor Policy Advisory Work Group was formed to develop the methods for assessing non-compliance with the policy and determining what sanctions can be applied and under what circumstances. This Workgroup is chaired by Julie Heimbach, M.D., and includes members of the MPSC and the Living Donor Committee. It was agreed that the Group should address all organs and that as it develops the proposal they should highlight the definitions of what would be considered in each Category (I-III) as described in the Appendix A of the Bylaws. Patient safety and significant process issues should be clearly identified in the policy.

The Work Group laid out the following goals for their work.

1. Develop a minimum set of criteria for granting designated program status to centers performing living donor transplants (completed for liver, pending for other organs).
2. Ensure adequate donor education/informed consent.
3. Work-up of potential donors: Should there be guidelines or a minimum set of required elements?

Update: The Joint Work Group met by conference call on April 16, 2007, to develop a proposal for consideration by the MPSC during its May meeting. The primary motivation for the development of these proposals is that the MPSC is about to begin the process of reviewing and approving approximately 240 programs that perform live donor kidney transplants. The Committee wants to be sure that these centers not only have the key experienced personnel in place, but also have the essential elements in place to be a live donor center. Additionally, if these proposals are approved, the existing application will be amended request additional documentation from the live donor liver applicants.

The Work Group developed, and with the endorsement of the MPSC, is proposing modifications to the Bylaws that pertain to programs that perform live donor kidney and liver transplants.

The issues discussed by the MPSC included:

- What are the key elements for programs that perform living donor transplants?
- It is important for the bylaws to be monitorable and not overly proscriptive.
- Independent Donor Advocate (IDA):
 - What is the specific function of a donor advocate?
 - How do you measure the adequacy of the IDA or of the proposals?
 - IDA or IDA team? Committee felt strongly that there should be an IDA member who is a physician and who is not involved with the evaluation and decision to transplant a potential recipient. The Committee agreed that the use of an IDA or IDA team should be flexible since different centers have different approaches.
 - Concern about identifying a person who can be totally uninvolved in transplant yet be knowledgeable and able to advise living donors.
- Develop a guideline for the committee to use when evaluating a center's performance relative to the IDA.

The Committee agreed that the Bylaws should delineate what a program must have in order to receive initial approval to perform live donor transplants and the requirements that must be met to maintain approval once it has been granted.

The proposal was forwarded to the Living Donor Committee for its input prior to being distributed for public comment.

Live Donor Kidney Transplant Program Application Process: During its January/February meeting the staff provided the Committee with an initial draft of the live donor kidney program application form for their input. The Committee was informed that once it finalizes a draft of the document, it will be forwarded to the Office of Management and Budget (OMB) for approval. During its May meeting, the Committee agreed that the application needs to incorporate questions based on the final version of the Bylaws that are under development.

10. Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): The Committee was updated by staff on the status of events surrounding the two live donor deaths that were reviewed under Policy 7.3.3. This Policy requires these reviews to ensure that there are no patient safety concerns or associated policy violations when a living organ donation results in an adverse outcome for the donor. If corrective actions were to be required, they would be stated in the findings, and reported to the Board of Directors.

Utilizing the Committee Management System, a Subcommittee of the MPSC initially reviewed the cases involving the deaths of live donors (kidney) at two transplant centers. They concluded that no further action was required in either case as there was not any evidence of policy violations and patient safety issues were not exposed. The Committee reviewed the findings of the Subcommittee during its May meeting and agreed that no further action was required in either instance. The Committee approved the following recommendation:

** RESOLVED, that the Committee accepts the report of the Subcommittee in response to the deaths of live donors at two transplant centers.

The Committee vote was unanimous.

The report will also be disseminated to the Living Donor Committee and to the centers where the events occurred.

11. Pancreas Outcome Analysis Model: During the July 12, 2006, meeting, the Data Subcommittee discussed the issue of pancreas (including kidney/pancreas and pancreas after kidney) program outcome monitoring. A number of committee members suggested that the Committee consider implementation of pancreas outcome monitoring. In turn, the SRTR was asked to evaluate potential models and possibilities available for increasing the sample size so the analytical model could be applied to pancreas programs. Currently the SRTR does publish outcome data for kidney/pancreas programs but there is no model for the evaluation of pancreas alone or pancreas after kidney one year outcomes. It is understood that some pancreas programs may still fall below the 10 or more transplants performed threshold, in which case the Subcommittee will follow the process currently utilized for small volume outcome reviews for other organs.

During the October 11, 2006, meeting, the Committee was informed that the SRTR was prepared to begin work to create the model. However, the Committee believed that the Pancreas Transplantation Committee needed to review the variables, including recipient and donor risk factors, before the model is developed. The Committee requested the Pancreas Transplantation

Committee discuss the variables to be included in an outcome analysis model for pancreas alone, pancreas after kidney, and simultaneous kidney/pancreas transplantation.

Update: During the May 2007 meeting, the MPSC was informed that the Pancreas Transplantation Committee canceled its March 2007 meeting, but will discuss the pancreas outcome analysis model at its May 18, 2007, meeting and will report back to the Committee for the August 2007 meeting.

12. Number of days a program has its waitlist inactive (but not membership): During its January/February meeting staff presented the Committee with an overview of the programs had periods when the Waitlist Program Status field was set to temporarily inactive during 2006, but the program had not inactivated its membership status. There were 21 programs (representing all organs) that had their waitlist set to “temporarily inactive” for 15 or more days. Seven of these programs had a cumulative waitlist inactive time of greater than 100 days.

The Committee agreed that further review of this data should be performed by the Data Subcommittee as part of its review of functionally inactive programs, and further recommended that letters be sent to those programs that currently have their waitlist default set to temporarily inactive and 15 or more consecutive days have passed. The letter should explain the bylaws relating to functional inactivity and seek information on the status of the program and its future plans.

Update: During its April 23, 2007, conference call, the Data Subcommittee reviewed data for programs with active membership status and inactive wait lists for less than 15 days; active programs that inactivated a wait list for greater than 15 days; and inactive programs with patients still on the wait list. Further investigation is required, including determination of programs that are single surgeon, as well as contacting the programs via telephone to confirm their knowledge of the issue. The Data Subcommittee will continue its discussion during its July meeting.

13. Proposal 2: Proposed Notice of Change to Policy 7.1.5 and Proposed Modifications to the Living Donor Registration and Living Donor Follow-Up Forms. The Committee discussed this policy proposal sponsored by the Living Donor Committee. This policy modification will fulfill an OPTN contractual obligation to collect information on all living donors at the time of donation and for at least two years after the donation. The Living Donor Committee is recommending that the two-year Living Donor Follow-up (LDF) form include the same data elements that are currently being collected at one-year post donation. The longer follow-up period will provide valuable information on the experience, safety, and health implications for living donors. Transplant center compliance with living donor follow-up is especially important since no alternative source of data exists.

Background: Currently, the recipient transplant centers of living donors report only six month and one-year follow up for living donors. The OPTN is now required to obtain two-year follow up data on all living donors. This additional data collection is consistent with the OPTN Principle of Data Collection to “ensure patient safety when no alternative sources of data exist.” The “operational statements for data collection” approved by the Board in December 2006 also state that (1) the OPTN will only collect data that is contracted by HRSA, and (2) that data for specific populations (e.g., Living Donors) may constitute exceptions to the Principles of Data Collection. There are currently no other sources of data for living donors that would allow the OPTN to meet this contractual requirement.

The MPSC discussed this proposal at length and while it supports the concepts, it expressed some

concerns and made several recommendations. One of the MPSC's jobs is to monitor programs and assess center performance so many of its concerns were related to the collection of specific data elements that allow it to effectively carry out its charge.

Concerns:

- Requirements must be reliably monitored in a way that will provide important information about program performance. What are the elements that can be monitored and used to give feedback to the programs and provide metrics for measuring performance? The data that is collected must be meaningful and measurable.

- The MPSC was unable to discern the goal behind the proposed requirements and specific data elements, and was concerned about its ability to use the requirements in the proposal for measuring program performance. The Committee thought that the Living Donor Committee's proposal should provide more detail and clearly identify the specific uses of the data that would be collected.
 - Is the goal of the proposal to provide data for evaluating overall center performance or the impact of donation on an individual donor, or both?
 - The Committee expressed its concern that the goal of measuring the impact of donation cannot be effectively met based on just two years of follow up data. It opined that Living Donor Follow-ups forms submitted at 6 months and one-year post donation may not really capture center related performance.
 - The Committee believed that the assessment could be broken down into three areas:
 - (1) Early problems: Finding out the frequency of problems that occur early after the initial donor procedure (define early – 6 month, 1 year, 2 years).
 - (2) Program specific performance: Are there programs that have more complications than expected with living donors and what are those data (i.e. high complication rates, failure of native organ, etc.)? How can expected rates be assessed?
 - (3) Long term health assessment: What happens to the donors beyond 2 years? The Committee opined that it was important that information regarding donors be collected well beyond two years.

Data Elements and Data Collection: The Committee agreed that it has to be specific about what data elements it needs in order to assess program performance. It raised the following questions:

- Within the proposed two year variables what are the key components for measuring the performance of a program that is doing live donors?
- Should a functional assessment be required at a minimum?

The Committee suggested that the Live Donor Policy Work Group design a questionnaire.

The Committee also discussed the burden that would be experienced by both the donor and the transplant program in providing the proposed follow up information and was concerned about the burden to the donor would decrease the likelihood of participation. They were particularly concerned about the need for donors to come into the transplant center or a local physician's office for tests and how such requirements could be enforced.

Recommendations:

- Put together a communications plan for the community and the public that includes how we are monitoring the short term adverse outcomes to ensure safety, what the approach is

that HHS has taken to the study of long term consequences, and how and if we are going to undertake the study of program performance.

- The Committee recommended that the option of using a telephone survey, such as the SF-12® or SF-36® Health Survey, to collect quality of life data should be considered in order to increase participation. A few organ specific questions could be added if permission to use these forms can be obtained. Use of the SF-12® or SF-36® form would provide the option of making data comparisons with the general population.
- What are the necessary data elements needed to assess early mortality and early complications and what is the best way to get that information?
 - What is the role of UNetsm based Patient Safety System?
 - What is the overall incidence of complications?
 - What information can be realistically collected and what are the mechanisms that would be most effective?
 - The Committee noted that long term complications and long term results could be reviewed utilizing the retrospective study that is already underway.

The Committee recommended that the joint Living Donor Policy Working Group be reformulated to ensure good cross communication between the two committees and to develop an alternative to the current proposal. It was suggested that a call between the committee chairs and UNOS staff leadership could help to identify the path forward.

** RESOLVED, that the Committee agreed to inform the Living Donor Committee that it supports the proposed changes to Policy 7.1.5 and the Living Donor Registration and Living Donor Follow-up Forms in principle, but it recommends changes to the two-year data elements be considered. The Committee suggested using the SF-12® Health Survey as a model and will develop an alternative form for consideration.

The Committee voted 16 For, 0 Against, 0 Abstentions.

14. Proposal 3: Proposed Modifications to Policy 7.3.3 “Submission of Living Donor Death and Organ Failure Data” sponsored by the Living Donor Committee. Under current policy, transplant programs must report all instances of live donor death and failure of the live donor’s native organ function within 72 hours after the center becomes aware of these events. This proposed policy modification defines living donor “native organ failure” as (1) placing living liver donors on the National Liver Transplant Waitlist and (2) living kidney donors requiring dialysis. This proposal limits the reporting period to five years, which will provide valuable information on the short-term health and safety implications for living donors.

Background: The Board of Directors resolved that transplant centers must immediately report any live donation-related deaths and organ failure that occur within the first six months post-transplantation to the Membership and Professional Standards Committee (MPSC). In response, the Living Donor Committee proposed a policy that would require immediate reporting of serious adverse events in living donors prior to normal reporting on the Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) forms. The policy was effective pending appropriate notice and simultaneous with public comment, which ended in July 2006. The Living Donor Committee further modified the policy language to clarify that adverse events in living donors would be reported through the UNetSM Patient Safety System. This system became operational in January 2007.

After review of this policy, the MPSC recommended that the Living Donor Committee further clarify the policy to define organ failure and to limit reporting to five years. The Living Donor Committee defined “organ failure” as either listing for transplant in liver donors or need for dialysis in renal donors. The Committee agreed to limit the reporting requirement to five years.

Update: The MPSC discussed the proposed changes to Policy 7.3.3 during its May meeting and suggested two changes:

- 1) To modify the proposed definition of native organ failure for kidney donors to include not only the need for dialysis but also transplant. The Committee noted that there are cases where the individual may be transplanted without undergoing dialysis.
- 2) The Committee discussed the criteria for reporting for a period of 5 years from the date of the donation and agreed the Policy should be reworded to remove the time limitation.

The Committee approved the reworded Policy as shown below in double underline/double strikeout.

**** RESOLVED**, that proposed Policy 7.3.3 *Submission of Living Donor Death and Organ Failure Data* be amended as set forth below.

7.3.3 Submission of Living Donor Death and Organ Failure Data. Transplant programs must report all instances of live donor deaths and failure of the live donor’s native organ function within 72 hours after of the programs knowledge becomes aware of the live donor death or failure of the live donors’ native organ function. Live donors’ native organ failure is defined as listing for transplant for liver donors and the need for dialysis or transplant in renal donors. These events will be reported to the MPSC for further review and reporting to the Board. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of five years from the date of the donation. The MPSC will review and report all adverse events to the Board.

The Committee voted 15 For, 0 Against, 0 Abstentions.

15. Proposal 4: Proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms. The MPSC considered the proposal from the Living Donor Committee that adds one new data element to the Living Donor Follow-Up (LDF) form and three new data elements to the Living Donor Registration (LDR) form. The additional data elements would document important information, including: attempts to contact a donor classified as “lost to follow-up”; the date and the living donor’s status during the most recent contact between the donor and the recipient transplant center; and whether living donor organ recovery and transplant of that organ occurred at the same center.

The Committee agreed to support the proposal as written.

**** RESOLVED**, that the Committee supports the proposed Modifications to the UNetSM Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms.

The Committee voted 16 For, 0 Against, 0 Abstentions.

16. Proposal 5: Proposed Modifications to Data Elements on UNetSM Deceased Donor Registration (DDR) Form.: This policy proposal would add new data elements to the OPTN Deceased Donor Registration (DDR) form. Collecting more specific details on the recovery process for individual DCD donors will help the transplant community develop transplant, donation and allocation policies, one of the OPTN guiding principles for future data management. In addition, the majority of these proposed data elements were recommended as a result of the 2005 National Conference on Donation after Cardiac Death.

The Committee discussed this proposal and agreed that that it was important to collect data that can be used to help predict which DCD's can be successful donors, and the percentages of usable and non-useable organs recovered.

** RESOLVED, that the Committee support the proposal as written with the following amendments:

- 1) Consider decreasing the frequency of serial data collected after a period of analysis.
- 2) Add pre-withdrawal of femoral cannulation; and
- 3) collect data on the patients who were attempted as DCD and the organs transplanted/not transplanted.

The Committee voted 20 for, 0 against, 0 abstentions.

17. Proposal 7: Proposed Modifications to Bylaws, Appendix A, Section 2.06A, (b), (3-7). The MPSC considered proposed Bylaw changes that would require Members to provide written notification to patients who are being evaluated for transplant, candidates on the waiting list, and transplant recipients within 30 days after the following adverse actions occur:

- Probation
- Member Not in Good Standing
- Suspension of Member Privileges
- Termination of Membership or Designated Transplant Program Status and
- Action Specified in OPTN Final Rule

Both patients being evaluated and candidates listed during the duration of the adverse action must also be informed. The objective is to provide prompt notification of Member violations that might affect treatment services and patient safety.

The Committee discussed this proposal during its May meeting and expressed the following concerns:

- Suggested development of a patient notice letter or language that ensures that the minimal information is being communicated to the candidates.
- Language doesn't apply to OPOs and Labs. Should they have to notify the transplants center they contract with if an adverse action has occurred?
- Doesn't differentiate between a program on probation and the center (i.e. systemic versus programmatic issues). Do the programs that were not at issue also need to notify their candidates?
- Concern about length of process between time of event and the time patients may be notified of the adverse action.
- What action can be taken if the hospital fails to notify patients?

The Committee agreed to approve the proposed changes to the Bylaws, Appendix A, Section 2.06A, (b), (3-7) as written, and recommends that language also be added to address the notification process for OPOs and histocompatibility laboratories.

** RESOLVED, that the Committee supports the proposed Modifications to Bylaws, Appendix A, Section 2.06A, (b), (3-7) as written. BE IT FURTHER RESOLVED that the Committee asks the Patient Affairs Committee to consider whether or not similar revisions to the Bylaws should be made to address public notification when the member is an organ procurement organization or histocompatibility laboratory

The Committee Voted 15 For, 0 Against, 0 Abstentions.

18. Web Based Center Profile: The MPSC continued its discussion of the center profile which is under development and will reside on the OPTN website. The goal of the site is to provide center specific information in a format that is easy for the public to understand. The Committee had previously reviewed the elements included in the dashboard and suggested incorporating local waiting times within DSAs. Additionally, they discussed displaying the surgical depth of the program by displaying information about the number of surgeons available to the program as listed in the Membership database; and the need to provide outcomes data for small volume transplant programs.

During its May meeting, the Committee discussed that need to be more public in acknowledging that they are actively involved in the assessment and correction of problems as they are identified; and that it is an ongoing process. They discussed the difficult balance of making information public while at the same time maintaining confidentiality and the integrity of the peer review process.

They agreed that information regarding the activities of the OPTN needs to be available including the various performance and policy monitoring methods that are used to review all members/transplant programs on an ongoing basis.

They also suggested adding the following to the webpage:

- A list of the centers that have reached the level that they require public notification along with the date they are released from review.
 - Aggregate data about the number and types of reviews the Committee is overseeing as a whole.
19. Metric to Monitor Activity: During its July 2006 meeting, the MPSC discussed whether to develop a metric for formally reviewing organ transplant programs that have an excessive delay between the time a patient is approved internally for transplant listing and is then actually activated on the waitlist. The Kidney Transplantation Committee asked the MPSC to consider establishing guidelines for evaluating program performance in this regard. This issue was raised when a kidney program requested from the Kidney Transplantation Committee waiting time modifications for 25 transplant candidates who were activated long after center wait listing approval was granted. The MPSC members agreed that this mistake was a patient safety issue, but they did not believe the authorization to monitor it was established in OPTN Bylaws or policy.

After discussing alternatives, such as reviewing center transplant candidate listing time intervals as part of the DEQ site survey or having the MPSC review committee referred unusual waiting time modification requests, it was decided to submit this issue to the Transplant Administrators Committee and organ specific committees for comment. The MPSC requested feedback on whether this metric is important and if so, what language should be used in developing bylaw and/or policy proposals.

During its May 2007 meeting, the Committee considered the feedback received from the various committees and the language in the Bylaws that requires that the candidate be informed, in writing, of their placement on the waitlist within 10 days of the decision. The Bylaws do not presently address the time between evaluation and listing.

Summary of Responses:

- Thoracic Organ Transplantation Committee: *“The Committee felt it was not necessary at this time but would continue to monitor the situation if it arises.”*
- Liver and Intestinal Organ Transplantation Committee: *“The Committee opined that this situation is not relevant to liver transplant programs since waiting time minimally affects their priority on the waiting list.”*
- Pancreas Transplantation Committee: *“One member remarked that the charge of the Committee is to increase the utilization of pancreata and expressed reluctance in adding the role of policing candidate listing to this charge. There was concern that such a metric might capture program activity that is readily explainable and not indicative of any policy compliance or other issues needing follow up. Rather than commenting on the appropriateness of this request, the Committee would like an update regarding the MPSC’s work in developing an organ turnaround review protocol and any related metrics associated with pancreas.”*
- The Transplant Administrators Committee (TAC): *“Committee members unanimously agreed that while some parameter might be established for use as a guideline that programs could measure internally, we would not endorse establishing a universal target or number because no one knows what it should be.”* They further pointed out that there are many common factors that can appropriately influence the timing for placing a candidate on the waiting list. While the TAC indicated that they did not think that the MPSC should take any action at this time, they suggested that a maximum suggested amount of time between acceptance and listing could be established as a guideline (e.g. 90 days).

The Committee noted that the incident that led to this discussion was likely an isolated event because most programs want to list their candidates as soon as possible. They also agreed that it would be difficult to monitor. In conclusion, they agreed that a new monitoring system or metric did not need to be put in place when it was an isolated event. They unanimously agreed that no further action was required.

20. UNOS Actions: During the May meeting, the Committee members agreed that actions regarding Bylaws and Policy, and program specific decisions made during the OPTN session would be accepted as UNOS actions.

** RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations. FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted was 18 For, 0 Against, 0 Abstentions.

**Attendance at the Membership and Professional Standards Committee Meeting
May 1 - 2, 2007**

Committee Members Attending

Timothy L. Pruett, M.D.	Chair
Niloo M. Edwards, M.D.	Vice Chair & At Large
Craig Lellehei, M.D.	Region 1
John A. Goss, M.D.	Region 4
Chris E. Freise, M.D.	Region 5
Rainer W. G. Gruessner, M.D., Ph.D.	Region 7
Rob J. Linderer, RN, BSN	Region 8
Patricia A. Sheiner, M.D.	Region 9
Santiago R. Vera, M.D.	Region 11
Juan D. Arenas, M.D.	At Large
Bonita Balkcom Guilford	At Large
Terry D. Box, M.D.	At Large
Thomas A. Gonwa, M.D.	At Large
Susan Gunderson, MHA	At Large
Julie K. Heimbach, M.D.	At Large
Donald E. Hricik, M.D.	At Large
Geoffrey A. Land, Ph.D.	At Large
Jill M. Maxfield, RN, CPTC	At Large
Jennie P. Perryman, RN, Ph.D.	At Large
Randall C. Starling, M.D.	At Large
Debra L. Sudan, M.D.	At Large
David Weill, M.D.	At Large
Renee Dupee, Esq.	Ex Officio
Michele Walton, RN, BSN	Ex Officio

Committee Members Unable to Attend

Cosme Manzarbeitia, M.D.	Region 2
Alan I. Reed, M.D.	Region 3
Jorge D. Reyes, M.D.	Region 6
Jeffrey D. Punch, M.D.	Region 10
Dale G. Renlund, M.D.	At Large
Randolph H. Steadman, M.D.	At Large
Christopher J. McLaughlin	Ex Officio

SRTR Staff in Attendance

Charlotte Arrington, MPH
Robert A. Wolfe, Ph.D.

UNOS Staff

Sally H. Aungier, Administrator, Membership Services
Betsy Coleburn, Review Board Coordinator
Rosey Edmunds, Membership Coordinator
Brandon Ellison, Compliance Analyst
Mary D. Ellison, Ph.D., MSHA, Assistant Executive Director for Federal Affairs
Suzanne Gellner, Assistant Director of Analysis & Due Process
Douglas A. Heiney, Deputy AED for Administration

Dave Kappus, Assistant Director, Membership & Policy
Karl McCleary, Ph.D., MPH, Director, Policy, Membership, and Regional Administration
Chantel Mitchell, Membership Coordinator
Joel Newman, Assistant Director, Communications
Jacqui O'Keefe, Performance Analyst Manager
John Rosendale, Biostatistician
Deanna Sampson, Director, Evaluation and Quality
Leah Slife, Membership Coordinator