

OPTN/UNOS Membership and Professional Standards Committee
Report to the Board of Directors
June 22-23, 2009
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to grant approval to one new individual member. (Item 1, Page 5)
- The Board of Directors is asked to grant full approval to two programs that have reactivated, and grant a one-year extension of conditional status to a program that performs living donor liver transplants. (Item 1, Page 5)

II. Other Significant Items

- Annual Committee Goals: During its March meeting, the Committee was presented with the Goals that had been approved for the year and the progress that had been made on those goals that were already underway. (Item 2, Pages 5-6)
- Program-Related Actions and Personnel Changes: The Committee reviewed 37 and approved 33 personnel change applications. (Item 3, Page 6)
- Due Process Proceedings: During the March meeting, the Committee conducted one interview with a member transplant center. (Item 4, Page 6)
- Performance and Certification Maintenance Work Group: The Certification Maintenance and Performance Metric Work Groups reported on its efforts to review the efficiency and effectiveness of the methods that are used for member evaluation on an ongoing basis, and making recommendations on improvements to the process. The Committee reviewed the comments received in response to the proposal to change the OPTN/UNOS Bylaws, to clarify the process for reporting changes in key personnel. The Committee agreed that it would continue to refine the proposal with the goal of presenting it to the Board in November 2009. (Item 5, Pages 7-9)
- Live Donor Adverse Events Reporting: As required in Policy 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 the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed one reported instance. (Item 6, Page 9)
- Preventing the Appearance of Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement: The Committee continued its discussion of concerns relating to a single surgeon being involved in the declaration of death in organ donors, procurement of the organs, and in transplant surgeries. The Committee reviewed draft

bylaw language that had been developed by an ad hoc subcommittee and agreed to further amend the draft language and to submit the proposal for public comment. (Item 7, Pages 9-10)

- **Living Donor and Intestinal Transplant Program Requirements:** The Committee was updated on the plans to review the bylaws related to living donor transplantation. A joint work group comprised of members from the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee has been formed to discuss this issue. The Committee also reviewed preliminary feedback from the Liver and Intestinal Organ Transplantation Committee on some questions regarding changes that had been discussed at a previous meeting and its status of developing requirements for intestinal transplant programs. (Item 8, Pages 10-14)
- **Living Donor Applications:** The Committee received a progress report on the status of the application process for the transplant programs that perform living donor kidney transplants. The Committee was also informed that the “request for additional information” that was sent out to all the living donor liver programs had been by all of the programs. (Item 10, Pages 14-16)
- **Proposed Bylaw Modifications to Reconcile Volume Requirements for Primary Transplant Physicians:** The MPSC considered an amendment to the bylaws that will reconcile the requirements in the conditional pathways with those bylaws related to training and experience. The Committee agreed to submit the proposed changes for public comment. (Item 11, Page 16)
- **Inactive Bylaw Modification:** During the March meeting, the MSPC discussed feedback from the November 2008 Board of Directors meeting during which, the Board approved further modifications to the bylaw language. Additionally, the Committee received an update to the Joint Patient Affairs Committee/MPSC Work Group. (Item 12, Page 16)
- **OPTN Notification of Potential Adverse Action by other Regulatory Agencies:** During its March 2009, meeting, the Committee reviewed existing and recommended modifications to the bylaw language that requires transplant programs, OPOs, and histocompatibility laboratories to notify the OPTN of threatened or real adverse actions taken by regulatory agencies. (Item 13, Pages 16-17)
- **Committee Review of ASTS Recommendations:** The Committee considered two proposals from the ASTS. Recommendations for Standards for Individuals Procuring Deceased Donor Organs for Transplantation”; and “Traveling Surgical Scholarship in Living Donor Liver Transplantation.” (Item 17, Page 19)
- **Islet Cell Transplant Program Oversight:** The program approval and recipient follow-up reporting bylaws relating to pancreas islet are not being enforced currently. The Committee discussed seeking clarification from HRSA of the OPTN's role in islet transplantation oversight. (Item 18, Page 19)
- **Pancreas Outcome Model:** During the March 2009 meeting, the MPSC considered a report from the Pancreas Transplantation Committee, including recommendations to

adopt the newly developed one-year patient survival model for MPSC use in analyzing pancreas transplant program outcomes. (Item 19, Pages 19-20)

- OPO Performance Metrics Work Group: The Committee was updated on the work of the OPO Performance Metrics Work Group, which is made up of members of the OPO Committee and the MPSC. It is tasked with developing performance metrics to maximize the utilization of organs. (Item 21, Page 20)
- Reports from the Organ Specific Committee regarding the Center Specific Reports (CSRs): The SRTR presented a summary of the Organ Specific Committee work regarding improving the center/program specific reports. The SRTR representatives will continue to update the MPSC on the progress of the improvements and when changes will be implemented into the model. (Item 23, Pages 20-21)
- UNOS Actions: 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 25, Page 21)

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Richmond, Virginia

James J. Wynn M.D., Chair
Carl L. Berg, M.D., Vice Chair

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on March 17-18, 2009, in Chicago, Illinois and on May 6, 2009, by conference call and Microsoft Live Meeting. The Committee's deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee is charged with determining that member clinical transplant centers, independent organ procurement agencies, independent tissue typing laboratories, and non-institutional members meet and remain in compliance with OPTN/UNOS Criteria for Institutional Membership. During each meeting, it considers actions regarding the status of current members and new applicants. The actions reported below were taken by the Committee during its March meeting.

The Committee recommended that the Board of Directors approve an application for a new Individual Membership (two-year term),

The Committee reviewed one liver transplant program holding conditional approval for performing living donor transplants based on the qualifications of the second primary surgeon. The Committee recommends that the Board of Directors now extend the conditional status for one additional year as permitted in the bylaws. The Committee also recommended that the Board approve the reactivation of two transplant programs.

2. Overview of Annual Committee Goals: During the March meeting updates were provided to the Committee on the goals that were approved for the 2007-2008, and 2008-2009 Committee Cycles. A list of the goals is provided below and each one is addressed in more detail later in this report.

Performance Measures

- Goal 1: Evaluate the use of OPO Metrics to assess performance. (Item 21)
- Goal 2: Complete a retrospective review of current processes and implementation of new performance measures. (Items 19)

Bylaws

- Goal 3: Review the transplant program bylaws related to staff and infrastructure requirements for changes to further ensure patient safety. (Item 5)
- Goal 4: Rewrite Bylaws to update format, use plain language. (Items 5,7,11,13,20)

Network Measures

- Goal 5: Initiate the application process for live donor kidney transplantation, and obtain additional information from programs that perform living donor liver transplants. (Item 10)
- Goal 6: Initiate and complete the audit of transplant surgeons and physicians & update the database accordingly to indicate which individuals meet the new criteria for the program to designate them as “additional” or “other” surgeon/physician. (Item 24)
- Goal 7: Collect and process Program Coverage Plans (primary physician, additional physician, etc.) from all existing transplant programs. (Item 24)
- Goal 8: Review transplant centers and OPOs that are not in compliance with the new Donation after Cardiac Death (DCD) Bylaws requiring that they have protocols to facilitate the recovery of organs from DCD donors. (Item 3)

The 2008-2009 OPTN Long-range Strategic Goals and Priorities as listed below were introduced to the Committee during the July 2008, meeting. They closely overlap the goals that are listed above.

- 1) Advise staff in the policy and bylaws rewrite project to improve format and use plain language [Operational Effectiveness]
 - 2) Develop OPO performance metrics in collaboration with OPO Committee [Maximum Capacity, Operational Effectiveness]
 - 3) Implement bylaws and policies pertaining to transplant programs that do living donor transplants and develop appropriate processes for overseeing compliance with OPTN requirements [Patient Safety]
 - 4) Develop transplant program scorecard (TCS report) for operational use by the MPSC [Operational Effectiveness]
 - 5) Develop processes and metrics for regular review of program-specific problems that prolong the time to transplant for waitlisted patients (e.g., Donor offer acceptance, turndown, and transplant rates), as cited in April 2008 Report of the GAO [Patient Safety]
 - 6) Explore the development of Maintenance of Certification concept and methodology as quality assessment and compliance initiative [Patient Safety]
3. Program-Related Actions and Personnel Changes: During its March meeting, the Committee reviewed and accepted programs changing status by voluntarily inactivating or withdrawing from designated program status., Additionally, during the March meeting, the Committee reviewed 37 and approved 33 Key Personnel Changes.
 4. Due Process Proceedings: During its March meeting, the Committee conducted an interview with one member transplant program that reported a living donor death to the Committee. The member was issued a Letter of Reprimand based upon violations of Policy 7.3.3. The member must submit updates to the Plan of Quality Improvement. A work group of MPSC members was established to conduct ongoing reviews of the members progress

5. Certification Maintenance and Performance Metric Work Groups: During its November 2007 meeting, the MPSC formed a work group to address committee goals. In particular, the work group needed to review the efficiency and effectiveness of currently used member qualification assessment methods and recommend improvements to the process. The Work Group was asked to consider whether or not the current level of program review is adequate to ensure ongoing compliance and competency, and if there were areas that could be improved.

The Work Group identified several areas of concern in the existing bylaws related to changes in key personnel:

- Members are unaware of the notification requirements in the bylaws and do not routinely notify the OPTN/UNOS immediately when they experience a change in key personnel.
- Members do not consistently submit completed key personnel change applications within 30-days of a change in key personnel.
- The majority of applications submitted are missing required information or documentation. It often takes months for members to supply follow up information as requested by staff or the MPSC so that they can be resolved. Some applications remain open or unresolved for extended periods in the review process. This delay increases the potential risk to patient safety, since the center has not demonstrated that it is staffed with individuals who meet the key personnel requirements.
- Centers that do not have a surgeon or physician on site who meets the key personnel requirements will submit applications naming unqualified individuals, seemingly in order to “buy time” while they recruit qualified individuals.
- Members seemingly presume that once an individual has been named in any application that they have been “UNOS certified” and that they don’t need to submit any new information regarding the individual’s ability to meet the requirements.

The Work Group suggested that the MPSC change the bylaw language regarding time limits for notifying and submitting applications to UNOS about changes in key personnel. The MPSC agreed that these changes will allow more timely oversight of the notification process and allow it to readily address the concern that some applications are drawn out for long periods because the centers do not submit complete information initially.

The Committee discussed whether or not it should further define “be notified immediately.” It agreed that immediate notification should be made no more than 7 days after a member transplant center is notified or becomes aware of a change in staff. This interpretation parallels similar CMS regulations for notification.

It was agreed that the transplant center would have 30 days to submit a complete application form before a change took place. Appendix A of the Bylaws presently defines the application process and the components of a complete application. If the application is not received by the specified due date one of the following actions may be taken:

- The MPSC can make a recommendation to the Board of Directors that the Board notify the Secretary, and/or

- It can take appropriate action in accordance with Appendix A of the Bylaws, including actions defined as adverse under Section 3.01A.
- Alternatively, if there are no doctors at the center who meet the requirements to serve as the primary transplant surgeon and physician, the center should immediately inactivate the affected program(s). Failure to take action by taking one of these steps will result in a recommendation to the Board as noted above.

The work group also proposed language that would address a change in the designation of the key person when the current primary has not left and remains actively involved with the program, i.e., they are still listed as an “additional” surgeon/physician. Additionally, the Committee agreed that if a program has staff on site who would meet the requirements for primary surgeon and physician, it may not be necessary for the program to inactivate while UNOS processes the application.

The Committee agreed that the requirements for reporting changes in primary lab directors, OPO Executive Directors and OPO Medical Directors should be reviewed by the specialists on the Committee and similar proposals developed.

Update:

The Committee distributed a proposal for public comment in February 2009. When it met in March, the public comment period was still open so the Committee was only able to consider some of the initial comments. The Committee agreed that amendments might be necessary and planned to meet again by conference call to consider all of the comments.

The Committee met by conference call on May 6, 2009, and considered all of the comments that had been received during the public comment period. Comments were divided into the following common themes:

Bylaw Related Comments

- Confusion between changes in key personnel and program coverage during vacations.
 - Remove 15 day language
- Suggested reinstatement process for returning key personnel.
- Need to address process/exceptions for departures with short or no advance notice
- 30 days is not long enough to complete an application.
 - Submission of transition plan in lieu of application
- Proposal does not mandate cooperation between centers when obtaining information (letters of reference, logs, etc.)
- Allow designation of alternate key personnel

Resources/Process Related Comments

- Increase education effort
 - Incorrect understanding in field about the process for reporting and obtaining forms.

- Access to application forms (see <http://www.unos.org/data/about/collection.asp>)
- Application is burdensome.
- Conduct root cause analysis to determine why applicants don't meet deadlines.
- Web-based process:
 - Desire to have web-based applications.
 - Transportability of information submitted in previous application when person relocates.
 - Develop web-based repository for individuals to house their logs, letters of reference, and other related documents.

The Committee agreed that this proposal was not time sensitive and that the comments that were received should be given ample consideration. The Committee was particularly concerned with the number of professionals who seemed to be misinformed about the process for submitting changes in key personnel and thought that an educational effort should also be initiated, starting perhaps with developing a FAQs sheet that is targeted to the transplant administrators.

An ad hoc work group was tasked with reviewing the proposal and the comments, and working with staff to develop a revised proposal for the MPSC's review during its July meeting.

6. Update on Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data): The MPSC reviews programs that report adverse events under Policy 7.3.3 (Submission of Living Donor Death and Organ Failure Data). This policy states that all transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program 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 listing for transplant or the need for dialysis in renal donors. Transplant centers must report these incidents through the UNetSM Patient Safety System for a period of two years from the date of the donation.

During its March meeting the Committee reviewed one case, the death of a living kidney donor reported by Center 44672C. The death occurred more than one year post-donation. The Committee agreed that no further action was required because there was not any evidence of policy violations and no patient safety issues were indicated.

7. Preventing the Appearance of Potential Conflicts of Interest Regarding Declaration of Death and Organ Procurement: The MPSC continued its discussion of an issue discovered during a peer visit. During the course of its review, the peer team noted concerns relating to a single surgeon being involved in the declaration of death in organ donors, procurement of the organs, and in the transplant surgery. The team informed the center at the end of the visit of the potential conflict this practice presents.

The MPSC discussed the issue at length on May 7, 2008, and referenced the Revised Uniform Anatomical Gift Act of 2006 (UAGA), Section 14, Part I, which states:

Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.

The Committee further agreed that the Bylaws and/or Policies may need to be amended to include language that addresses the UAGA and requires surgeons within a transplant program involved in declaration of donor death not be involved in organ procurement and transplantation. A subcommittee was appointed to facilitate this review. Lynn Driver was appointed as the chair. Other participants include Rich Luskin, and Drs. Ben Hippen, George Loss, and Christopher Marsh. The Subcommittee first met by conference call on September 5, 2008. During the October MPSC meeting, a draft proposal was presented to the Committee for input. It was agreed that the Ethics and OPO Committee should be asked for feedback on the proposal prior to it being further considered by the MPSC.

Update: During the March 2009 meeting the Committee reviewed a revised proposal that was developed based on the feedback received from the Ethics and OPO Committees. This proposal takes a simpler approach by defining the members obligations to following their own state laws regarding anatomical gifts. The Committee unanimously agreed that this proposal should be distributed for public comment in June.

8. Living Donor and Intestinal Transplant Program Requirements: Several issues have arisen over the past months that have made it apparent that the current bylaws and policies specifying the program requirements for living donor transplantation need further review. That has come into particularly acute focus as conditionally approved living donor liver transplant programs have reached the end of their conditional approval periods without successfully identifying a second qualified primary surgeon, and as centers have completed their living donor kidney transplant program applications. As a result, the MPSC has asked a Joint Work Group comprising members of the MPSC, Living Donor Committee, Pediatric Transplantation Committee, Kidney Transplantation Committee, and the Liver and Intestinal Organ Transplantation Committee to “review the living donor program requirements for currency and relevance, determine if the original goal of the requirements is being met, and recommend Bylaw modifications as needed.”

Some of the issues the MPSC has asked the Work Group to address are:

- The living donor requirements largely specify the program components and surgeon experience that are appropriate for centers that care for living donors and perform living donor nephrectomy or hepatectomy. The Bylaws, however, are written as if they apply to the transplant program that performs living donor liver and kidney transplants rather than the center that actually provides the donor care and surgery. The MPSC has encountered situations where the living donor care and surgery is provided in one fully-approved program and the transplant itself performed in another transplant center. The MPSC therefore asks that Work Group consider Bylaw revisions that would clarify that the living donor requirements apply to the member center providing the donor care and performing the donor surgery.
- Clarify which center is responsible for pre- and post-donation living donor-related activities when the donation takes place in one institution and the transplant in another.
- Clarify which center is responsible for pre- and post-donation care when the donor participates in paired donation at a center geographically removed from his or her local transplant center.
- Determine whether the experience requirements for surgeons performing adult-to-pediatric segmental liver donation should be different from the requirements for surgeons

performing right donor hepatectomy as required for adult-to-adult transplantation.

- Clarify whether surgical experience obtained in split or reduced deceased donor hepatectomy should be considered relevant for living donor hepatectomy, and review the list of CPT codes currently used by UNOS staff to determine whether case should be used to satisfy the surgical experience Bylaw provision.
- Consider whether distinct experience criteria should be established for surgeons performing living donor liver transplants (as opposed to living donor hepatectomy).

Other areas for review may include:

- Development of Living Donor Program performance metrics.
- Definition of functional inactivity for living donor transplant programs.
- Development of policy, guidelines and educational resources related to the UNOS kidney paired donation system under development.
- Re-examination of requirements for living donor nephrectomy programs – possible conditional pathways for approval.
- Reevaluation of the requirement that experience be documented with both laparoscopic and open donor nephrectomy, given the accumulated experience with and progressive maturity of skills in laparoscopic donor nephrectomy.
- Revisions to the OMB (Office of Management and Budget) approved application forms for Living Donor Transplantation.

The Work Group will hold its first conference call on May 22, 2009.

During its March meeting the Committee acknowledged that the Liver and Intestinal Organ Transplantation Committee (Liver Committee) had responded to a November 10, 2008, memo in which Dr. Wynn asked them to consider a number of questions related to living donor and intestinal transplantation. MPSC received feedback from the Liver Committee in a memo dated January 5, 2009. These responses will be provided to the newly formed joint Work Group for their consideration. A summary of the questions posed by the MPSC and the Liver Committee's responses follows:

Living Donor Transplantation

- A) Is there a requirement to require that each program have at least two surgeons who meet the requirements for living donor hepatectomy? Should the level of experience in living donor hepatectomy and major hepatic surgery required for approval as a qualified donor hepatectomy surgeon be the same for surgeons performing adult-to-adult lobar transplantation and those who perform only adult-to-pediatric segmental hepatic transplants?

Liver Committee's response: *The Committee addressed these two questions together.*

- *Left lateral segment – The Committee agreed there was no reason to have two surgeons meeting the requirements for this procedure.*
- *Right lobe – What was the basis for the original requirements? The rationale was if there was a complication related to the donor, there would be two qualified surgeons available in case one surgeon was unavailable. The Committee recommended the following for adult-adult right lobe live donor procedure:*
 - *One qualified live donor liver transplant surgeon (according to UNOS Bylaws) and,*
 - *A liver transplant surgeon or hepatobiliary surgeon practicing in a transplant center and performs at least 20 major liver resections per year.*

B) Is there a need to continue to require that, for programs that have received only conditional approval due to the living donor hepatectomy inexperience of one of their surgeons, “both of the designated surgeons must be present at the donor’s operative procedure?”

Liver Committee’s response: *The Committee agreed that both surgeons should be present. It was noted that if the changes proposed in the previous question are put in place, this conditional pathway will no longer be necessary.*

C) Are the most appropriate cases being used to demonstrate experience with liver surgery in both the full and conditional pathways? The bylaws currently state these surgeons must “have demonstrated experience as the primary surgeon or first assistant in 20 major hepatic resectional surgeries (to include living donor operations, splits, reductions, resections, etc), 7 of which must have been live donor procedures, within the prior 5-year period.”

Liver Committee’s response: *The Committee agreed that “splits” should be removed from the bylaw requirements. The Committee also felt that CPT code 47399 “Unlisted liver procedure” should be removed.*

D) The MPSC, at its last meeting, approved changes in bylaw language that would clarify that the living donor requirements apply only to programs performing the living donor surgery. These changes are intended to address the situation where the donor surgery is performed in an approved living donor liver center with the transplant itself being performed in a separate transplant center. We would ask for your committee’s input on this proposal in advance of its being submitted for public comment.

Liver Committee’s response: *The Committee agreed that this is acceptable, however; if this change is specifically referring to pediatric liver transplantation and the scenario where the donor hepatectomy is being done at an adult transplant center and the transplant is being done at the pediatric center, then it needs to be clear in the bylaw language. The Committee agreed that language should be added for clarification, especially with kidney paired donation becoming commonplace in transplantation and the possibility of live donor liver paired donation is likely in the future as well.*

E) This bylaw change noted in the preceding paragraph could conceivably result in a circumstance where the surgeon performing the living donor liver transplant had relatively little or no experience with living donor hepatectomy. Should we establish separate

experience thresholds for surgeons who perform the living donor liver transplant itself, perhaps incorporating experience accrued in the transplantation of deceased donor liver segments or reduced grafts?

Liver Committee's response: *The Committee did not feel that requirements should be created for surgeons that are performing the adult to pediatric live donor liver transplant recipient procedure.*

- F) Should liver transplant programs that perform living donor hepatectomy and/or transplants be reviewed for functional inactivity in the living donor portion of the program specifically and, if so, what metrics should be used to initiate review of the programs?

Liver Committee's response: *The Committee agreed that it is important to set some minimum activity level for living donor hepatectomy/transplants. Due to the small volume at most centers, the Committee agreed that if you do not perform at least one living donor transplant within a one year period, the MPSC will review the program.*

- G) Requirements for Intestine Transplant Programs. During its October 2008, meeting the MPSC also agreed to ask the Liver Committee for input regarding activity levels for intestinal transplant programs as discussed by the Performance Metrics and Certification Work Group and for an update regarding their efforts to develop membership criteria for intestinal transplant programs. At present, intestinal transplant programs are not evaluated on an ongoing basis for activity, performance, or staffing.

Currently, the only UNOS requirements for intestine programs are that the center has an approved liver program. When a transplant center wants to perform intestine transplants, it submits a letter to the Membership Department, complete a staffing survey indicating the key staff members, establish a UNetSM site administrator for the program, then the Membership Department will report to the MPSC that the program has initiated this process.

The Liver Committee reported to the MPSC in its January 5, 2009 memo, that it had reviewed a draft document from the American Society of Transplant Surgeons (ASTS) that established criteria for ASTS Program Accreditation in Intestine Transplantation and agreed it was a good starting point for establishing intestinal transplant program criteria within the OPTN/UNOS Bylaws. The ASTS requirements include performing 10 intestinal transplants annually for two years and if an individual has completed a fellowship in a program that meets these requirements, they would be eligible to serve as the director of an intestine program. The Liver Committee noted that if it wants to parallel the fellowship requirements of the ASTS recommendations, they should still develop additional pathways to accommodate those individuals that have on-the-job experience or who trained well before the time ASTS certified these programs.

The Liver Committee proposed the following criteria for intestinal transplant surgeons:

- Training at an ASTS approved fellowship (in programs that perform at least 10 intestine transplants in 2 years in addition to 5 procurements)
- Completion of a liver transplant fellowship followed by an additional year of training in intestinal transplantation at an ASTS approved program.
- Experience pathway - For intestines, perform 10 intestine transplants and 5 procurements as primary surgeon or first assistant over a 2-5 year period in order to get *conditional*

approval. Perform 15 intestine transplants and 5 procurements as primary surgeon or first assistant over a 2-5 year period in order to get *full approval*.

- Must be a liver transplant surgeon.

The Liver Committee also reported that it had discussed the requirements for the primary physician for an intestinal transplant program. It agreed that with intestinal transplants, the medical management of intestinal transplant patients is extremely important and that issues with nutrition and gut rehabilitation might require a multi-disciplinary team. The Liver Committee decided to form a subcommittee to evaluate the data, and work out the details and further address these complicated issues.

9. Submission of Living Donor Data: In a June 15, 2008 letter, the Living Donor Committee (LDC) asked the MPSC to:

- Determine a minimum thresholds for Living Donor follow-up form accuracy and completion (decrease the number of donors categorized as “lost to follow-up”)
- Ensure 6 month, one year and two year Living Donor Follow-up forms are submitted at appropriate times
- Commit to an annual review of living donor follow-up

Dr. Wynn asked that a joint Living Donor Committee-MPSC work group be formed to work on this issue. The charge to the Work Group was to assist the LDC in determining what the response should be to those centers that do not meet the threshold in regards to forms submission; and to determine what constitutes a successfully completed form as opposed to an incomplete yet submitted form.

During the March 2009, meeting the MPSC was informed of the efforts made by MPSC members to assist the LDC with this project. It was observed that the LDC had reached a point where it could continue the project without the further assistance from the joint work group so it was dissolved.

10. Living Donor Applications: The Committee discussed the implementation of the application process for programs that perform living donor kidney (LDK) transplantation and the collection of additional information from the programs that are currently approved to perform living donor liver transplants.

Living Donor Kidney (LDK) Transplantation: The Committee was informed that a notice had been distributed that described the schedule for the mailing and submission dates for the living donor kidney application. Applications were distributed by region in October, November, and December 2008 to all centers that have OPTN approved kidney transplant programs. As shown in the table below, members were given 90-days to submit a complete application or an Opt Out form if it does not offer LDK transplants.

Table 1: LDK Application Distribution Schedule

LDK Application Distribution Schedule			Number received
Regions	Date Sent	Due Date	
2, 5, 11	10/7/2008	1/7/2009	81
1, 3, 7, 9	11/3/2008	2/3/2009	64
4, 6, 8, 10	12/2/2008	3/2/2009	69
Total			214

Applications were sent out staggered by region so that staff and committee members would not be overwhelmed with all them being returned at the same time. Once the staff verifies that an application is complete, it is assigned to two MPSC members to review. The subcommittee will make a recommendation to the MPSC regarding whether approval should be given to the applicant. All applications will then follow the standard MPSC process and be placed on a consent or discussion agenda for consideration during the next scheduled meeting. The MPSC will forward its recommendations for approval to the Board of Directors. The plan is for the Board to approve all living donor kidney program applicants at the same time so that no program will be unfairly advantaged by the approval process timeline. The goal is for all existing approved kidney programs to have their living donor component approved at the November 2009 Board of Directors' meeting.

Living Donor Liver (LDL): The Committee was also updated on the status of the request for additional information from the programs that are already approved to conduct living donor liver transplantation.

Background: Additional requirements that address the following areas were added to the Bylaws in September 2007:

- Requirement for IDA or donor advocate team.
- Program required to have and follow protocols for all phases of living donation.
- OPTN review of program records for compliance with bylaws.

In 2005, UNOS finalized the criteria that must be met by liver transplant programs in order to perform living donor liver (LDL) transplants, and the approval process was initiated. Based on those criteria, programs approved once they met the requirements. At its September 2007 meeting, the Board of Directors adopted additional criteria for approving programs to perform living donor liver transplantation. Since all previously approved programs must now meet the additional provisions, programs were asked to submit additional information that documents that they satisfy the additional requirements.

Progress Report: The request for additional information was distributed to the 65 programs that perform living donor liver transplantation with a submission deadline of October 24, 2008. All approved living donor liver transplant programs centers have submitted the additional information. The supplemental information is currently being reviewed by Subcommittees comprised of two MPSC members. A Subcommittee can recommend to the MPSC whether the members satisfy the additional requirements and whether continued program approval is appropriate. In those instances where the Subcommittee has concerns with requirement compliance the member will be notified and given an opportunity to address the Committee's

concerns and questions. The goal is for all existing programs to have completed the process by June 2009.

11. Proposed Bylaw Modifications to Reconcile Volume Requirements for Primary Transplant Physicians: During its October 2008 meeting, the Committee discussed potential changes to the bylaws related to the experience and training requirements for primary transplant physicians. In July 2006, a MPSC working group recommended and received approval for changes to the experience levels that primary physicians needed to meet for kidney (45), liver (50) and pancreas (8). These changes were not carried over to the bylaws for conditional pathways, so technically a conditionally approved primary physician could be fully approved at the end of their one-year conditional period with significantly fewer cases being followed.

This was not the intent of the original bylaw change so the MPSC was asked to consider modifying the conditional pathway volume requirements. The Committee agreed that modifications needed to be made and input was provided by committee members regarding what changes would be appropriate.

During the March 2009 meeting the MPSC considered an amendment to the bylaws that will reconcile the requirements in the conditional pathways with those for training and experience. The Committee agreed to submit the proposed changes for public comment. The proposed changes will be distributed in the June 2009 public comment document.

12. Inactive Bylaw Modification: During the March meeting, the MSPC discussed feedback from the November 2008 Board of Directors. During that meeting, the Board of Directors suggested modifications to the bylaw language, including the addition of a clause for programs that may inactivate during natural disasters.

The Committee was also provided with an update from the Patient Affairs/MPSC Joint Work Group. This Work Group was charged with drafting language that transplant programs could use to notify patients of periods of inactivity, including waiting list and formal inactivation of member status. The work group met on February 23rd and agreed that at a minimum, three different types of letters need to be crafted: 1) Program that inactivates its waiting list for 14 consecutive days or more; 2) Program that inactivates its waiting list for 28 cumulative days or more; and 3) Programs that inactivate its membership status or relinquish designated program status. The work group also suggested the creation of a flow chart to help transplant program staff identify which language should be used. UNOS Staff will draft language and the flow chart for consideration by the work group during its April 20, 2009, meeting.

During the March 2009 meeting, the Committee also discussed implementation of the bylaw. Implementation is pending based upon programming requirements in the wait list function of UNetsm. The MPSC requested that staff investigate the ability to implement the Data Subcommittee's monitoring efforts as codified in the bylaw, independent of the programming requirements. Internal staff discussions were to be scheduled with the goal of finding a way to operationally apply the inactive bylaw changes prior to the implementation of programming.

13. OPTN Notification of Potential Adverse Action by Other Regulatory Agency: During its March 2009, meeting, the Committee reviewed existing bylaw language that requires transplant programs, OPOs, and histocompatibility laboratories to notify the OPTN of threatened or real adverse actions taken by regulatory agencies. Appendix B specifies that Members threatened with an adverse action from a regulatory agency must submit all materials relating to the action to

the OPTN within five (5) days of the Member's notice of such action. This bylaw was adopted concurrent with public comment in June 2006.

Of particular concern is those members applying for CMS approval based on the transplant program conditions of participation. The MPSC is aware that there are likely numerous transplant programs that have been threatened with decertification based on lower than expected outcomes and/or inadequate transplant volume. However, UNOS has only received such notice from six transplant programs, only three of whom met the five-day deadline.

The Committee discussed the intent of the bylaw and recognized that it is likely many programs in this situation are already under Data Subcommittee review. Further, MSPC members agreed that the requirement to submit all materials relating to the issue was burdensome to the Member, particularly given the process for approval and appeal can take six-months or more before final action is taken.

At the conclusion of the discussion, the Committee initially recommended that the existing bylaws be modified to strike all requirements for OPTN notification of threatened or real adverse action. However, based on further discussion and comments, the following resolution was passed:

** RESOLVED: Distribute for public comment modifications to Appendix B of the Bylaws to require OPTN notification of final adverse actions taken by other regulatory agencies against OPOs, Histocompatibility Laboratories, and Transplant Programs within 10-business days of Member notification; and,

** FURTHER RESOLVED: Distribute to OPTN Membership a reminder of the existing bylaw requirement, noting planned modifications to be distributed for public comment, and the submission of the initial and final letter from the regulatory agency will satisfy the document submission requirement.

The MPSC's vote was unanimous, with 23 For, 0 Against, 0 Abstentions.

14. OPO Committee Response Concerning Directed Donation Referral: The Committee requested that the OPO Committee consider OPO responsibilities in approaching and informing all families about directed donation, and to consider developing standards or guidelines regarding how families are approached and informed about directed donation during the consent process. The MPSC reviewed the OPO Committee's response during its March 2009 meeting.

The OPO Committee considered whether a standard should be developed that encourages OPOs to include directed donation as an option for a family, and discussed the appropriateness of some form of guidelines that would demonstrate how directed donation should be introduced to the family. The OPO Committee agreed that current OPO practice is varied throughout the United States in this area. OPTN Policy states that directed donation organs must be allocated to a specific person and must be unsolicited. Since there are no OPTN policies dealing with how consent should be obtained, and since directed donation is only a small part of the consent process for organ donation, the OPO Committee agreed that directed donation should not be singled out for policy development.

15. OPO Committee Response Concerning Labeling Referrals: During its March 2009 meeting, the Committee reviewed the OPO Committee's responses to two referrals regarding organ and vessel labeling. At its October 2008 meeting, the Committee referred questions to the OPO Committee

regarding the inclusion of serologies on vessel labels and whether modifications could be made to UNetSM that would enable all required label information to be generated by UNetSM and printed.

At its October 16, 2008 meeting, the Committee reviewed potential violations of Policy 5.7.6.2 (Vessel Storage) at two transplant centers. UNOS site surveyors conducted transplant center site surveys, and found that the vessels stored by the transplant centers did not include serology results on the labels. The two transplant centers responded to the site surveyors' report that the local OPO did not record serology results on the label attached to the vessel container. This OPO instead attaches a copy of the serology results (source documents) to the outer bag containing the vessel container. In response to UNOS inquiry, the OPO contended that this procedure decreases the chance that OPO staff will incorrectly transcribe these results onto the vessel label.

As a result of this situation, the Committee requested that the OPO Committee review Policy 5.7.6.2 to address whether the policy language reflects the committee's intent and current needs and practices within the OPO community, and to modify the policy language if necessary.

During its December 2008 meeting, the OPO Committee considered the request from the MPSC to review the issue concerning extra vessel labeling practices. The OPO Committee, as one of its goals, is reviewing existing policies for clarity. To help achieve this goal, the OPO Committee has rewritten Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials); however, the policy still requires that the vessel container be labeled with the serology results. The OPO Committee stated that the OPO that has not recorded the serology results on the label but attaches a copy of the source documents to the outer bag that contains the vessel container is therefore in violation of current policy.

In addition to the Committee's review of mislabeled vessels, at the July and October 2008 meetings, the Committee reviewed seven instances in which OPOs mislabeled organ or tissue typing material containers. During the October 2008 meeting, the Committee expressed concern about the number of mislabeling incidents reported through the UNetSM Patient Safety Portal. The Committee recognizes that human error is inevitable when donor information is recorded manually on the required labels, and asked that the OPO Committee review the current organ labeling practices and consider whether modifications could be made to the UNetSM system to enable the relevant information to be printed, thereby eliminating manual transcription errors.

The OPO Committee considered the request from the MPSC to review the current organ labeling system and consider modifications to UNetSM during its December 2008 meeting. Although the OPO Committee agreed that it would be helpful if UNetSM generated vessel labels, members recognized the potential cost incurred from such changes to the system. In light of recent direction that no new changes will be made to DonorNet® for some months, the OPO Committee agreed that when resources are available, the Committee will consider further investigation into the possibility of creating labels through the DonorNet® system. In the meantime, the OPO Committee formed a subcommittee to review the current labeling system and to determine if there are elements on the labels contributing to the errors being made.

16. OMB Form Changes: The Committee was briefed on the process for preparing the OMB data collection forms package. The current forms expire in November 2010. OPTN committee review of the current forms is to take place during Spring of 2009. All potential additions to the forms must have a strong rationale and meet one of the Principles of Data Collection. They must also be submitted for public comment. The Ad Hoc Data Management Group will review all proposed additions to the forms and make recommendations to the Policy Oversight Committee (POC). Following public comment, the POC will submit a package of all recommended changes

to the forms for consideration by the Board of Directors at the March 2010 meeting. Of note, the OMB approved membership applications forms do not expire until February 2011.

17. Committee Review of ASTS Recommendations: The Committee considered two proposals from the ASTS: “Recommendations for Standards for Individuals Procuring Deceased Donor Organs for Transplantation” and “Traveling Surgical Scholarship in Living Donor Liver Transplantation.”

The Committee considered a proposal from the ASTS entitled “Recommendations for Standards for Individuals Procuring Deceased Donor Organs for Transplantation.” The ASTS asked that the OPTN committees “*review these recommendations for the purposes of developing policies to oversee solid organ procurement.*” The Committee appreciated having the opportunity to comment on these recommendations but was not inclined to pursue the development of parallel policies at this time.

The Committee also considered a proposal from the ASTS “Traveling Surgical Scholarship in Living Donor Liver Transplantation.” The Committee did not see any conflict with the OPTN/UNOS bylaws and suggested that participants were submitting documentation for OPTN/UNOS consideration they would need to support their surgical experience by submission of an operative note in the English language.

18. Islet Cell Transplant Program Oversight: The program approval and recipient follow-up reporting bylaws relating to pancreas islet are not being enforced currently. The Committee discussed seeking clarification from HRSA of the OPTN's role in islet transplantation oversight. No further action is scheduled to take place until the Federal Government determines internally whether this is a solid organ transplant or another form of medical therapy, that should not be placed under the OPTN's purview.
19. Pancreas Outcome Analysis Model: During the October meeting, the Committee was updated on the effort to develop a Pancreas Outcome Analysis Model.

During the March 2009 meeting, the MPSC considered a report from the Pancreas Transplantation Committee, including recommendations to adopt the newly developed one-year patient survival model for MPSC use in analyzing pancreas transplant program outcomes. The Pancreas Committee also recommended that the MPSC delay use of a graft survival model until the Subcommittee could complete more analysis to improve the index of concordance to be that of the lung, kidney, and liver models. The MPSC agreed with these recommendations and asked the SRTR to provide patient outcomes analyses once available. The Committee requested that the Pancreas Transplantation Committee continue to update the MPSC on its work on the graft survival model.

Included within the memo from the Pancreas Transplantation Committee was a recommendation to post only the one-year patient survival model on the public websites. The MPSC responded noting that publication of these data is an SRTR contractual and NOTA requirement, and therefore the MPSC is not the correct body to consider this recommendation. The Pancreas Transplantation Committee was urged to talk with SRTR and HRSA representatives about modifying the models currently published.

20. Goals for Bylaws Rewrite: Staff updated the Committee on one of the goals established for the Committee by the President - the re-write of the existing Bylaws. The purpose of the revision is to improve clarity regarding member rights and responsibilities, and OPTN/UNOS

responsibilities. Clarity will be achieved by the use of plain language and logical organization of the content. Staff will continue to address the goals of the rewrite project as sections of the bylaws are developed or modified.

21. OPO Performance Metrics Work Group: The OPO Performance Metrics Work Group, chaired by Charles Alexander, comprises members of the OPO Committee and the MPSC and is tasked with developing performance metrics to maximize the utilization of organs. The group first met in April 2008 and requested a data analysis from the SRTR to develop a model for calculating expected yield per donor. An ordinal logistic regression model was based on OPTN data from 6/1/2000 – 5/30/2007 and included data on donors from whom at least one organ was transplanted. Factors in the model were derived from the deceased donor registration form. Factors that were considered to reflect OPO practices were deliberately excluded from the model. The model concordance was 0.8. From the model, 15 of 58 DSAs were identified as having an actual number of organs transplanted per donor that was significantly below expected ($p < 0.05$). An enhanced analysis was requested that will include more recent data as well as donors from whom no organs were transplanted.
22. Proposed Modifications to the Bylaws Article I (Members); Section II (Board of Directors); and Section VI (Officers): During its June 2008 meeting, the Board of Directors approved modifications to the OPTN Bylaws to eliminate the elector system for Histocompatibility Laboratory and Medical/Scientific Members. The Board of Directors requested that the Committee review the possibility of eliminating the elector system for Public Organization Members and Individual Members. In the event that the elector system is eliminated for these classes of members, each public organization member and each individual member would be permitted an individual vote in OPTN/UNOS affairs. At the October 2008 meeting, the Committee discussed this option and recommended to the Board of Directors that the elector system be retained for Public Organization Members and Individual Members.

During its March 2-3, 2009 meeting, the Board of Directors again requested that the Committee review the possibility of eliminating the elector system for Public Organization Members and Individual Members. When it met on March 17-18, the Committee again reviewed the pros and cons of eliminating the elector system for these two groups, including requests from two public representatives.

The elector system only goes into effect when the number of members exceeds 12 public organization members or 12 individual members. Presently, neither category has 12 or more members but the numbers in each category fluctuate over time since non-institutional members do not always seek successive 2-year terms.

Committee members expressed concern that while the number of members in these classes are presently low, one organized group could adversely affect the OPTN process and resources. After discussion, the Committee acknowledged the Board's request but maintained its previous decision that the elector system should not be further modified at this time

23. Reports from the Organ Specific Committee regarding the Center Specific Reports (CSRs): The SRTR presented a summary of the Organ Specific Committee work regarding improving the center/program specific reports, noting that the Thoracic Organ Transplantation Committee was the only one that appeared to have completed the project to date. The SRTR representatives will continue to update the MPSC on the progress of the improvements and when changes will be implemented into the model.

Of note, the thoracic outcomes analysis time period cohorts will be aligned with the abdominal methodology in July 2009 based on the implementation of a six-month follow-up form for thoracic recipients.

24. Other Committee Goals: During its March 2009 meeting, the Committee was informed that two goals remaining from 2007-2008 have been completed.

Goal 6: Initiate and complete the audit of transplant surgeons and physicians and update the database accordingly to indicate which individuals meet the new criteria for the program to designate them as “additional” or “other” surgeon/physician. The collection of this information from existing programs is complete.

Goal 7: Collect and process Program Coverage Plans from all existing transplant programs. The collection of this information from existing programs is complete.

25. UNOS Actions: During the March meeting the Committee members unanimously agreed that actions regarding Bylaws, 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.

**Participation at the Membership and Professional Standards Committee Meetings
March 17-18, 2009 and May 6, 2009**

NAME	POSITION	Attended July 22-24, 2008	Attended Oct 15-16 2008	Attended Jan 27, 2009 Call	Attended Mar 17-18 2009	Attended May 6, 2009 call
James Wynn MD	Chair	X	X	X	X	X
Carl Berg MD	Vice Chair/Reg Rep	X	X	X	X	X
Paul Morrissey MD	Regional Rep.	X	X	X	X	X
Lynt Johnson MD, MBA	Regional Rep.	X	X	X	X	
George Loss Jr, MD, PhD	Regional Rep.	X	X	X	X	X
David Nelson MD	Regional Rep.	X	X	X		X
Christopher Marsh MD	Regional Rep.	X	X	X	X*	X
Karen Nelson Ph.D., D(ABHI)	Regional Rep.	X	X	X	X	X
Yolanda Becker MD, FACS	Regional Rep.	X	X	X	X	X
Michael Voigt MD	Regional Rep.	X	X	X	X	
David Conti MD	Regional Rep.	*	X		X	
Lynn Driver CPTC	Regional Rep.	X	X	X	X	
Charles Alexander RN, MSN, MBA, CPTC	At Large	X	X	X	X	
Sharon Bartosh MD	At Large		X	X	X	X
Tim Brown	At Large	X	X	X	X	X
Jonathan Chen MD	At Large	X	X	X	X	
Todd Dewey MD	At Large	X	X			
Barry Friedman RN, BSN, MBA, CPTC	At Large	X	X	X	X	X
James Gleason	At Large	X	X	X	X	X
John Herre MD	At Large	X	X	X	X	X
Benjamin Hippen M.D.	At Large	X	X	X	X	
Donald Hricik MD	At Large	X	X		X	X
Ian Jamieson MBA, MHA	At Large	X	X	X	X	X
Richard Luskin MPA	At Large	X	X	X		X
Jerry McCauley MD, MPH	At Large	X	X	X	X	X
Patricia McDonough RN, CPTC, CCTC	At Large	X		X	X	X
Brendan McGuire MD	At Large	X	X	X		
Michael Mulligan MD	At Large	X	X			X
Claus Niemann M.D.	At Large	X		X	X	X
Fuad Shihab MD	At Large	X	X	X	X	X
Mark Zucker MD, JD, FACC, FACP	At Large	X	X	X	X	X
Christopher McLaughlin	Ex Officio	X	X			
Robert Walsh	Ex Officio	X	X	X	X	X

NAME	POSITION	Attended July 22-24, 2008	Attended Oct 15-16 2008	Attended Jan 27, 2009 Call	Attended Mar 17-18 2009	Attended May 6, 2009 call
Charlotte Arrington MPH	SRTR Liaison	X	X	X	X	
Douglas Schaubel Ph.D.	SRTR Liaison	X				
Robert Wolfe, Ph.D.	SRTR Liaison		X		X	
Jack Kalbfleisch	SRTR Liaison			X		
Emily Messersmith	SRTR Liaison			X		
Sally Aungier	Committee Liaison	X	X	X	X	X
David Kappus MAS	Committee Liaison	X	X	X	X	X
Tyrone Brown	Support Staff				X	
Elizabeth Coleburn	Support Staff	X	X	X	X	
Erick Edwards Ph.D.	Support Staff	X	X	X	X	
Mary D. Ellison, Ph.D.	Support Staff	X	X	X	X	
Suzanne Gellner JD, CHC	Support Staff	*	X	X	X	
Linda Gobis	Support Staff	X	X	X	X	
Molly Massey	Support Staff				X	
Karl McCleary Ph.D., M.P.H.	Support Staff	X	X			X
Joel Newman	Support Staff		X	X	X	
Jacqueline O'Keefe MBA	Support Staff	X	X	X	X	X
Amy Pugh	Support Staff					X
Amy Putnam	Support Staff				X	
John D. Persons III, Esq.	Support Staff		X	X	X	
Leah Slife	Support Staff					X
Robyn Zernhelt	Support Staff			X	X	X

* Participated by conference call