Interim Report of the
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
March 28-29, 2012
Chicago, IL

The Membership and Professional Standards Committee (MPSC) met on March 28-29, 2012, in Chicago, Illinois and considered the following items:

I. Action Items for Board Consideration:

The Committee will ask the Board of Directors to approve the following recommendations during the June 25-26, 2012, meeting:

New Membership
- Grant approval to 2 new transplant hospital members, including approval of 3 new programs in these hospitals.
- Grant new two-year terms to 6 non-institutional members.

Existing Membership
- Fully approve 1 new program in an existing transplant hospital;
- Fully approve 1 new program component in an existing transplant hospital;
- Grant full approval to 8 programs that reactivated.

II. Old Business

- Annual Committee Goals: During its March meeting, the Committee was presented with the goals that had been approved for the year and the progress made on those goals that were already in process.

- Program-Related Actions and Personnel Changes: The Committee reviewed and approved 42 transplant program personnel change applications. Additionally, the Committee reviewed eight applications for changes in primary laboratory directors and approved four; and was notified that the four OPO's had changed either their medical director or executive director. The Committee will also notify the board of directors that 10 programs inactivated and that 3 programs ceased performing organ transplants.

- Due Process Proceedings and Informal Discussions: During the March meeting, the Committee conducted 5 interviews with member transplant hospitals and organ procurement organizations.

- Bylaws Rewrite Project: The work group chair and the staff updated the committee on the status of the bylaws rewrite project. The proposal was released for public comment December 2, 2011- January 31, 2012. A final proposal will be presented to the Committee during its April 20, 2012, conference call.

- Modifications to Appendix A of the Bylaws: The work group chair and staff updated the Committee on the status of the due process bylaws rewrite project (new Appendix L). The proposal was released for public comment February 1 – April 6, 2012. A final proposal will be presented to the Committee during its April 20, 2012, conference call.

- Modified Flagging Methodology: During the March meeting, the Committee reviewed the second cycle of simulation data comparing the results of the proposed modified flagging methodology with the existing flagging methods. Based on this review, the Committee approved the modified flagging methodology. Proposed bylaw language will be drafted for MPSC approval and will be distributed for public comment.

- Composite Pre-Transplant Metric (CPM): A review of the work performed and the synopsis of responses received was given. The work group is waiting for new data from the SRTR before analyzing what actions to consider.

- OPO Metrics: During the March meeting, the focus group reported on its progress in codifying the review process and tools for use by the Performance Analysis and Improvement Subcommittee (PAIS), upon implementation in July. The focus group recommended that upon initial identification of an OPO performing below expected, an inquiry letter will be sent to the OPO requesting the OPO provide an assessment of their performance, results of reviews conducted, and resolutions implemented. The focus group also created an Expanded Questionnaire for some situations where the PAIS may want to gain additional/more detailed information regarding OPO operations and copies of procedures and protocols. The focus group also identified data elements to aid PAIS members when reviewing an OPO's response to an inquiry. Finally, the focus group recommended that the development of a formal process diagram be postponed until after the PAIS gains some experience with the reviews. The MPSC approved the focus group recommendations to proceed with implementation in July 2012.

- Continuous Outcomes Monitoring (CUSUM): The SRTR presented the concepts of control charting for monitoring process improvement in post-transplant survival rates. The need for implementing different criteria for different types of programs (e.g., small volume versus large volume) was emphasized. The fact that all programs will eventually "signal" was also pointed out. The MPSC took no action based on the presentation.

- Compliance with Bylaws regarding Key Personnel Changes: Improvements in the timely key personnel change notification and application submission was noted. The new process for discussing the programs not complying with the key personnel change reporting requirements with the MPSC chair works well. Nine cases of possible non compliance were discussed with one case being determined out of compliance and the program was issued a notice of uncontested violation by the Committee. The process will continue and the results reported to the Committee.

- Compliance with Requirements for Director of Liver Transplant Anesthesia: On February 1, 2012, each approved liver transplant program (128 programs) was asked to supply the name of an individual who would meet the designation requirements as director of liver transplant anesthesia. When the MPSC met 16 programs (44.4%) had not yet complied with the request. There was an April 16, 2012, submission deadline. The Committee approved sending the non-compliant hospitals one more notice after April 16, informing the programs that this was the last notice and failure to comply will result with referral to the Committee for discussion and possible consequences at the July meeting.

- Peer Visit Definitions: Changes in Committee processes have resulted in an increased use of peer visits and recent feedback from peer team participants has identified a need for clear

definitions of peer visits and the type of peers selected to serve, as well as a clear focus of the particular peer visit. During the March meeting, the Committee approved new definitions for peer visits as well as the proposed committee process when a peer visit is recommended.

- Pancreas Outcomes Model: The SRTR presented proposed modifications to the 1-year graft and patient pancreas survival outcomes models. The SRTR will release the July 2012 PSR outcomes data to programs' private sites and will also make this data available to the Committee. All pancreas programs will be notified in the fall of 2012, that the Committee will begin implementing the pancreas outcomes review process in January 2013.

- Performance Analysis and Improvement Subcommittee (PAIS) Report: The PAIS met on February 27, March 2, and March 23, 2012, to continue its review of transplant programs that exhibited lower than expected patient and/or graft survival rates; small volume programs that experienced at least one death and/or graft failure within one year of transplant; and functionally inactive programs. The Subcommittee made its recommendations to the full MPSC during the March 28-29, 2012, meeting.

- Policy Compliance Subcommittee Reports: The Policy Compliance Subcommittee (PCSC) met on March 27. The PCSC discussed general issues as well as standard, periodic site surveys; member complaints; observed or reported potential policy violations, and organ specific committee referrals. In addition, the PCSC received updates on members that are continuing in monitoring. The PCSC made its recommendations to the full MPSC during the March 28-29, meeting.

III. New Business

- Collaboration between the Living Donor Committee and DEQ for the Implementation of New Living Donor Policies: Over the course of the three-day Committee meeting (including the Policy Compliance Subcommittee (PCSC)) meeting, implementation of the living donor policies scheduled for presentation to the Board of Directors in June was discussed several times. The Chair and various members of the Committee expressed concern that transplant hospitals may have difficulty implementing the new policies based on the review of current issues that were presented to the Committee for a number of living donor kidney programs. As a result, the Chair proposed a resolution requiring the Living Donor Committee to work with the Department of Evaluation and Quality to develop, in effect, an implementation plan including forms, the DEQ monitoring and evaluation plan and other resources for members.

- Transplant Program Quality and Surveillance: A consensus conference was held in February 2012 to discuss the current SRTR Program Specific Reports (PSR), risk adjustment factors, additional statistical methods, data collection elements, and types of monitored outcomes. The SRTR presented recommendations from the consensus conference work groups. The MPSC took no action based on the presentation.

- The Committee reviewed the following bylaw and policy proposals that were distributed for public comment (3/16 – 6/15/2012).

    - Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors (LDC): Under this proposal, existing policy would be modified to require members to report to the OPTN Contractor any unexpected potential or proven living donor-derived disease transmission, including infections or

malignancies. Current OPTN/UNOS policy requires specific infectious disease testing for all deceased organ donors. It also requires that any unexpected potential or proven disease transmission, including infections and malignancies, discovered after donation be reported to the OPTN Contractor.

The Committee agreed to support the proposal and asks that the Living Donor Committee work with DEQ staff to produce sample forms or templates in order to improve compliance.

- Proposal to Establish Kidney Paired Donation (KPD) Policy: This proposal sponsored by the Kidney Transplantation Committee converts the existing OPTN Kidney Paired Donation (KPD) Pilot Program rules, housed in the OPTN KPD Pilot Program Operational Guidelines, into OPTN policy. The full range of adverse actions will be available to the MPSC for violations of KPD policy, up to and including designation of member not in good standing. The policy also includes additional elements of potential donor informed consent that are specific to KPD and requirements for how the OPTN Contractor will conduct matching in the OPTN KPD Program. The proposed changes would consolidate all rules for the OPTN KPD Program into a single location and allow the MPSC to follow its standard processes for potential violations of KPD policy.

  The Committee unanimously agreed to support the proposal.

- 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.

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