

**Interim Report of the
OPTN/UNOS MEMBERSHIP AND PROFESSIONAL STANDARDS COMMITTEE REPORT
December 4-5, 2012
Chicago, IL**

The Membership and Professional Standards Committee (MPSC) met on December 4-5, 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 2013, meeting:

Existing Membership

- Fully approve 2 new programs in existing transplant hospitals;
- Fully approved 3 Medical/Professional Organizations for two year terms.
- Grant full approval of 1 program component in an existing transplant hospital that was previously conditionally approved;
- Grant full approval to 3 programs that reactivated.

The Committee discussed an application for a key personnel change in an existing transplant program, and did not approve the application. The program has been provided with options for action, and the application may be discussed again at future meetings.

II. Old Business

- Annual Committee Goals: During its December meeting the Committee discussed a number of the goals that had been approved for the year and the progress made on each.
- Program-Related Actions and Personnel Changes: The Committee reviewed 71 and approved 70 transplant program personnel change applications. Additionally, the Committee reviewed and approved three applications for changes in primary laboratory directors; and was notified that six OPO's had changed either their medical director or executive director. The Committee will also notify the board of directors that 8 programs or living donor program components inactivated and that 6 programs or living donor program components ceased performing organ transplants.
- Late Notification of Key Personnel Changes: The Committee discussed 2 transplant hospitals that submitted notice of key personnel changes after the primary surgeon had already left the hospital. The Committee issued a Notice of Uncontested Violation to each hospital.
- Due Process Proceedings and Informal Discussions: During the December meeting, the Committee heard a presentation from a member hospital that requested reactivation of one of its transplant programs. Additional information was requested from the program.

- Live Donor Adverse Events Reporting: As required in Policy 12.8.4 (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 6 reported instances and is not recommending any further action to the Board for 5 of them. The sixth program had voluntarily ceased transplanting and was being allowed to resume performing transplants. The Committee will monitor its compliance with its corrective action plan.
- Modified Flagging Methodology: The SRTR presented a different approach for the MPSC to consider regarding changes to the flagging criteria used for analyzing one-year post-transplant graft and patient outcomes. This new approach is using a Bayesian Methodology that the SRTR will be implementing for all program specific reports over the next several years. The MPSC discussed this approach in comparison to the modified flagging methodology that was approved for public comment during the July meeting. At the conclusion of the discussions, the MPSC rescinded its previous recommendation to send out the modified flagging criteria for public comment and requested additional analysis to compare the current flagging methodology, the modified flagging criteria, and the Bayesian methodology as well as implications for pediatric transplant hospitals, should the MPSC recommend adopting the Bayesian approach. The MPSC will consider results of the analysis during its April 2013 meeting.
- Composite Pre-Transplant Metric (CPM): The staff presented an overview of the CPM project and progress to date, providing summary information regarding the study participants and responses received. The results showed a relationship between CPM and the number of key personnel associated with a program, although this trend was not statistically significant. The CPM work group will meet again in early 2013 to consider next steps and additional analyses for MPSC consideration.
- Program-Specific Reports (PSR) - Reports Delay: The Performance Analysis and Improvement Subcommittee (PAIS) discussed interim plans for programs already reporting for lower than expected outcomes based on the delay in program specific reports. The PAIS recommended that the programs showing improvement, based on peer review, could be conditionally released. The programs would be informed that based upon peer review, committee members found evidence of improvement; however, when the next PSR is delivered, the program's outcomes would be reviewed and, if the program is flagged as performing below expected, they would be reintroduced to PAIS monitoring. Otherwise, their conditional release would become unconditional.
- Updates to OPO Flagging Criteria: The SRTR presented a summary of changes to the OPO Performance Metrics statistical analysis. The first change related to the use of the Lung pO₂ terminal value inclusion in the heart, liver, lung, and pancreas models. Feedback received noted that it would be better to use the Lung pO₂ terminal value divided by the FiO₂ value. This change has improved the fit of the model. More substantive discussions revolved around replacing the existing indicator "organ was recovered outside of the contiguous 48 states" with variables indicating the organ was recovered in Alaska, Hawaii, and Puerto Rico/Virgin Islands. The

SRTR presented four options for the PAIS to consider. Ultimately, the MPSC supported the focus group recommendation for making no changes to the existing geographic indicator and to blank out the expected yield for only the heart yield of the Hawaiian OPO.

- Bylaw Proposal - Requests for Exceptions based on Geographic Isolation: Language was presented to the Committee to be considered for release for special Public Comment. This proposed bylaw would allow for the MPSC to recommend that the Board of Directors consider approval of a non qualifying transplant program applicant that is located in geographically isolated area. “Geographically isolated” was defined as located entirely within a state or commonwealth noncontiguous with the mainland United States. This includes, but is not limited to, Alaska, Hawaii, and Puerto Rico. The proposed language was sent to the Executive Committee in December 2012 for approval to release for Public Comment and subsequent Board approval consideration.
- Single Programs/Multiple Hospitals: HRSA requested that the Committee readdress the possibility of utilizing single transplant program approval for more than one transplant hospital. The Committee reviewed past discussions on how it previously had previously handled the issue. A workgroup was put together to reexamine the matter and it will report back the Committee in 2013.
- Intestinal Transplant Program Requirements: The Liver and Intestine Committee presented the criteria it had developed for the designation and approval of an intestine transplant program. The MPSC was appreciative of the work done, but still had questions regarding the expressed requirements and how practical they were. The Committee asked that this not go out for Public Comment and be studied again by both groups. This was agreed to and these requirements will be brought back for further discussion in 2013.
- Standard for Defining Proposed Primary Surgeon/Physician Currency (Project): The Committee briefly discussed the current standard in the Bylaws for demonstrating currency of the primary surgeon/physician. The staff solicited volunteers for a workgroup to identify possible improvements to the Bylaw.
- Proposal to Require Reporting of Every Islet Infusion to the OPTN Contractor within 24 Hours of the Infusion: The Committee considered the proposal to amend the bylaws which is being sponsored the Pancreas Transplantation Committee. After participating in a presentation the Committee had no comments or expressed concerns regarding this proposal.
- Revisiting Pediatric Pancreas Program Status Active, Approval Not Required: The Committee discussed requests from two pediatric hospitals seeking permission to perform combined organ transplants, one organ being a pancreas, under the special “Active, Approval Not Required” status granted to them for structural integrity usage of the pancreas in multivisceral organ bloc transplants. They were requesting to transplant diabetic pediatric patients under this status. The Committee declared that the diabetic pediatric patient receiving a pancreas transplant, needs to receive it at an OPTN designated and approved pancreas transplant program. The “Active,

Approval Not Required” status does not cover pancreas transplantation in the diabetic pediatric patient.

- Assessing Transplant Program Competency: A broad discussion was held regarding whether or not the current processes effectively measure transplant program competency. The metrics used may not look at all the factors which are expected from a competent transplant program. This was the beginning of a longer and more complex dialogue.
- Performance Analysis and Improvement Subcommittee (PAIS): The Subcommittee met on November 26, and December 4, 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 Committee during the December 4-5, 2012, meeting.
- Policy Compliance Subcommittee Reports: The Policy Compliance Subcommittee (PCSC) met on November 7, and December 4, 2012. 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 December 4-5, meeting.

III. New Business

- 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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