OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
March 26-27, 2014
Chicago, IL

Carl L. Berg, M.D., Chair
Jonathan M. Chen, M.D., Vice Chair

Work of the full committee on March 26-27, 2014, is summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors.

Committee Projects

1. **Proposed Patient Notification of Lack of Transplant Functional Inactivity:**

   As part of its role to monitor compliance and patient safety, the Committee conducts reviews of functionally inactive programs that have not performed a transplant during a defined period. Based on concerns that the level of transplant activity at some programs that are repeatedly identified for functional inactivity are too low for a program to remain current with both surgical skills and programmatic administrative competence, the Performance Analysis and Improvement Subcommittee undertook an extensive review of the thresholds and process for review of functional inactivity. The overwhelming majority of programs identified for functional inactivity are pancreas transplant programs.

   Following this review, the Committee developed a proposal to provide, through a requirement for patient notification, candidates and potential candidates with information about the program's activity levels. The notification will allow patients to make informed decisions about whether to move to another more active program or multiply list at another program.

   The proposal was distributed for public comment during the Fall 2013 public comment cycle. At the March 2014 meeting, the Committee approved responses to public comment and will recommend that the Board of Directors approve the proposed modifications to the Bylaws.

2. **Proposal to Revise the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews:**

   As part of its role to monitor compliance and patient safety, the Committee conducts reviews of transplant program post-transplant outcomes to identify underperforming programs and work with those programs to implement performance improvement measures. The principal tool utilized by the Committee to identify programs that may merit closer review is performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR). Using data analysis provided by the SRTR and UNOS staff, the Committee develops thresholds for flagging those programs that may warrant closer review by the Committee. As part of its efforts to periodically review and evaluate the flagging threshold, the Committee, in collaboration with the SRTR, has spent several years reviewing alternative flagging mechanisms and thresholds to reduce the number of false positive flags and maximize the number of true positive flags. The Committee developed a proposal to better identify those transplant programs that may be

underperforming in the area of patient and graft survival. The Bylaw proposal adopts the Bayesian methodology and establishes new thresholds for identification of programs for review.

The proposal was distributed for public comment during the Fall 2013 public comment cycle. At the March 2014 meeting, the Committee approved responses to public comment and a recommendation that the Board of Directors approve the proposed modifications to the Bylaws.

3. Transplant Hospital Definition Project:

The Committee received an update regarding the work group's efforts to improve the definition of a transplant hospital member in the bylaws. The goal is for the Committee to consider proposed bylaw language when it meets in July. If the Committee approves the proposal, it could be distributed for public comment during the fall 2014 review period. If the proposal succeeds in public comment the Board of Directors could consider it for approval during its June 2015, meeting.

4. Quality Assessment and Process Improvement Requirement (QAPI):

During member reviews, the Committee has noted that members who are having difficulty with compliance or performance often do not have well developed quality assurance performance improvement (QAPI) programs. The Committee concluded that there appears to be a correlation between underperformance in the areas of compliance and outcomes and the lack of a robust QAPI program. Currently, the OPTN bylaws and policies do not contain a requirement for a QAPI program. As a result, the Committee does not have a basis for taking action when there is a finding that a member's QAPI program is inadequate. The Committee requested development of an OPTN QAPI requirement.

At the March 2014 meeting, the Committee approved proposed bylaw language for a quality assurance performance improvement requirement to be sent out for public comment in fall 2014. The Committee will review monitoring options for this proposal at the July 2014 meeting.

5. Composite Pre-Transplant Metric (CPM):

At the December 2013 meeting, staff presented an overview of the progress made over the last 4 years regarding CPM and the recommendations of the CPM Work Group. There was consensus that the Committee should proceed with public comment in the fall on this metric. Recent concerns raised regarding the component metrics will be referred to the CPM Work Group for their review, with a goal of providing proposed bylaw language for consideration by the Committee at a June conference call.

6. Data Submission & Accuracy in Reporting:

Policy 18.1 (Data Submission Requirements) requires members to submit data to the OPTN through the use of standardized forms. However, Policy 18.1 does not explicitly state that the data submissions must be accurate or that members must be able to provide documentation to verify the accuracy of their data submissions. The Committee has historically agreed that the need for accurate data is implied within Policy 18.1, as is

the member's obligation to provide documentation to verify the data's accuracy. This proposal change modifies Policy 18 to state explicitly that members must submit accurate data and that members are responsible for providing documentation to verify the accuracy of their data. This proposal was distributed for Public Comment in on March 14.

During its March 2014 meeting, the Committee was informed that the proposal is on the regional meeting non-discussion agenda. Public comments for this proposal will be reviewed during the July committee meeting. The proposal is scheduled to be presented to the Board at its November 2014 meeting.

7. **Bylaw Proposal to Allow a Recommendation from the MPSC to the Board of Directors for Approval Consideration of a Non Qualifying Transplant Program Applicant Located in a Prescribed Geographically Isolated Area:**

   The proposed bylaw language makes available a mechanism by which the MPSC can recommend to the Board of Directors that the Board might consider designating and approving a transplant program that cannot meet key personnel qualifying criteria because the applicant is located in an acknowledged geographically isolated area. This proposal was distributed for Public Comment in on March 14.

   During its March 2014 meeting, the Committee was informed that the proposal is on the regional meeting discussion agenda, however, preliminary feedback indicates resistance to providing a mechanism for considering program qualification exceptions. Public comments for this proposal will be reviewed during the July committee meeting. The proposal is scheduled to be presented to the Board at its November 2014 meeting.

8. **Currency Bylaw Reassessment Project:**

   During the March MPSC meeting, the Committee was informed that the Joint Society Policy Steering Group is asking to provide input on the primary surgeon and physician qualification topics and concepts the MPSC work group is addressing. A joint societies working group will be formed with representatives from AST, ASTS, and NATCO. This group will also include three MPSC Members as non-voting members. Once the working group recommendations are agreed on, they will be forwarded to the MPSC primary qualifications work group for further discussion.

9. **Criteria for Intestine Surgeons and Physicians (Joint project led by Liver and Intestinal Transplantation Committee):**

   This proposal defining a designated intestine transplant program and establishing minimum qualifications for primary intestine transplant surgeons and physicians was distributed for public comment on March 14. The Committee continues to support the establishment and approval of these requirements but made several suggestions for changes to the Liver and Intestinal Transplantation Committee.

10. **Pediatric Transplantation Training and Experience Considerations in the Bylaws (Joint project led by the Pediatric Transplantation Committee):**

    The Committee reviewed the Pediatric Transplantation Committee's progress in developing requirements for every transplant program intending to transplant patients younger than 18 years of age, to have specifically designated individuals who serve as the pediatric primary surgeon and the pediatric primary physician. This proposal includes kidney, heart, liver, and lung transplant designated primary pediatric primary surgeons and physicians. The consensus of the Committee is that the proposal can move forward to public comment but they suggested changes and asked to review the draft language before public comment.

Review of Public Comment Proposals (from other committees)

11. **Clarify Requirements for Blood Type Verification & Align with CMS Regulation where Possible:**

    This proposal was distributed for public comment on March 14, and it is part of a comprehensive effort to improve the clarity and efficiency for ABO determination, reporting, and verification requirements. Specifically, this proposal seeks to further reduce accidental ABO incompatible transplant risk, address gaps, and strengthen checks and balances to improve safety. The chair of the Operations and Safety Committee presented the proposal and responded to questions from the Committee. The Committee did recommend any changes to the proposal.

12. **Require Reporting of Aborted Living Donor Organ Recovery Procedures:**

    Under this proposal, an aborted living donor organ recovery procedure would become a new category of living donor adverse event that recovery hospitals would need to report through the UNet℠ Improving Patient Safety Portal. Additionally, the proposal would clarify current living donor adverse event reporting requirements by eliminating some redundant sections of policy.

    The Committee reviewed and supported the proposal and offered the following suggestions:

    - Clarify in Table 18-4 that "receives anesthesia" means induction of general anesthesia.
    - Recommend reporting when the recipient surgery is aborted due to an adverse event and that in turn results in the donor surgery also being aborted.

Other Committee Actions:

13. **Pancreas & Islet Bylaws Review:**

    The Pancreas Transplantation Committee's work on the proposed bylaw language modifying the minimum qualifications for primary pancreas and pancreas islet cell transplant surgeons and physicians was presented to the Committee for comment.

14. Education & Communication: Effective Practices & Process Improvement:

The MPSC heard a presentation from the Operations and Safety Committee - "Sharing Lessons Learned". It suggested a path forward on how the MPSC can share safety events, lessons learned, and prevention strategies to give members ideas and tools that they can use within their own settings to prevent safety situations and avoid repeating past mistakes, while at the same time protecting and maintaining peer confidentiality. This initiative was approved as a part of the Strategic Plan.

15. Collective Wait time transfer (Operations & Safety):

The Operations & Safety Chair presented a draft of proposed bylaw and policy changes, which would authorize a process (tool) so the OPTN can perform collective wait time transfers on behalf of multiple patients switching from a long-term inactive or withdrawn transplant program to an accepting one under a consensual agreement. This process is rarely needed, but when the situation occurs it is time consuming and susceptible to errors so a possible patient safety concern. The Committee did not understand the intent and need for this process. The view expressed was that this would force patients from long-term inactive or closed programs on non-receptive programs. The proposal was returned to Operations & Safety for further refinement.

16. Vascularized Composite Allograft (VCA) Requirements:

A brief presentation was made to the Committee regarding the work of the newly formed OPTN Vascularized Composite Allograft (VCA). The presentation included the proposed bylaw language establishing membership criteria for any currently approved OPTN member submitting a request to be designated and approved for a vascular composite allograft (VCA) transplant program. The Committee commented on the complexity of defining a VCA organ but did not recommend any changes to the proposed language.

17. Site Survey Innovation:

Phase 1 of this project is complete. The feedback received from Members, leadership and surveyors identified the areas of consistency, communications, priority setting and sharing of information as needing improvement. As a result, internal processes are undergoing improvement. In Phase 2, steps are being developed to make the suggested improvements. The Committee will be involved in these discussions, and its guidance will be required regarding the composition and use of scorecards in assessing compliance and how to assess and utilize submitted member CAPs (corrective action plans). Identified process changes will be incorporated into the OPTN evaluation plan.

Summary of Peer Review Actions:

18. Member Related Actions and Personnel Changes:

The Committee is charged with determining that member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants.

The Committee took the actions reported below during its meeting and will ask the Board of Directors to approve the following recommendations during the June 23-24, 2014, meeting:

New Members
- Fully approve 3 new histocompatibility laboratories
- Fully approve 9 individuals, medical/scientific organizations, and public organizations members for two year terms

Existing Members
- Fully approve 2 transplant programs
- Approve 1 transplant program reactivation
- Approve 1 transplant program reinstatement of primary physician
- Grant full approval to 2 program previously at 12 month conditional approval

Program-Related Actions and Personnel Changes:

The Committee reviewed and approved 68 transplant program personnel change applications. Additionally, the Committee reviewed and approved one application for a change in primary laboratory director. The Committee also received notice that five programs inactivated, and that one member and its program, one program and two living donor components at remaining member hospitals withdrew from membership.

The Committee discussed and approved a status change to full approval from conditional approval for one program.

Late Notification of Key Personnel Changes:

The Committee discussed two OPOs that had not met the notification requirements in the Bylaws. The Committee issued a Notice of Uncontested Violation to the both members.

Live Donor Adverse Events Reporting:

The Committee reviewed eight reported cases: six living donor deaths, one non-utilized organ, and one organ failure in a donor. The Committee is not recommending any further action to the Board at this time for any of the issues.

Next Scheduled Meeting(s)

- June 17, 2014 (conference call)
- July 8-10, 2014 (in person)
- December 9-11, 2014 (in person)