

OPTN/UNOS Liver and Intestinal Transplantation Committee
Meeting Summary
November 6, 2014
Conference Call

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Discussions of the full committee on November, 6 2014 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting Summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov/>.

Committee Projects

1. Redesigning Liver Distribution

During the last Committee meeting the rosters for the Ad Hoc Subcommittees on Redesigning Liver Distribution were drafted, each composed partly of members of the committee and partly of additional subject matter experts. These working groups will address three key focus areas: metrics to assess geographic disparity, logistical/transportation considerations, and financial issues. Additionally, the Liver Utilization subcommittee will be reconvened to address issues related to decreasing liver discards in order to increase the number of livers available for transplantation.

The work groups will meet several times by conference call between November and April to develop recommendations to be shared with the full committee by the spring of 2015 to aid in refinement of existing concepts or development of new ones. Currently the Committee is considering dates and locations for the spring forum, but anticipates a mid-late May event. The Committee will receive monthly updates on the Ad Hoc Subcommittee's progress in developing their recommendations.

Review of Public Comment Proposals

2. Definition of a Transplant Hospital

The current definitions of a transplant hospital that are found in OPTN Bylaws and Policies have not been modified since they were first adopted by the Board of Directors in 1986. Medical systems and hospitals have evolved, making the current transplant hospital definitions too simplistic, and vulnerable to interpretation. Specifically, the current definitions lack distinguishing detail for assessing institutions that consist of multiple "hospitals" transplanting the same organ type at geographically separate sites. Allowing transplants of one organ type to occur at multiple facilities under the umbrella of a single, approved transplant hospital complicates the OPTN's obligation, and the Membership and Professional Standards Committee's (MPSC) responsibility to monitor these hospitals for transplant outcome performance, compliance with OPTN expectations, and potential patient safety issues.

The proposed clarification of OPTN Policy and Bylaws will state that a transplant hospital is characterized by each organ type only being transplanted in a "single, discrete geographic location." Adopting this as an inherent characteristic of a transplant hospital means that transplant outcomes, OPTN compliance, and patient safety issues can be traced back to one specific transplant facility. Additionally, when data are combined from

more than one facility, issues at one site can go unnoticed if the other facility performs substantially more transplants. If you review aggregate data, the more active facility could mask the problems at the other facility.

One member suggested that the MPSC could require centers to report data from each individual site. The Scientific Registry of Transplant Recipients (SRTR) would then report outcomes by center and by site, ultimately allowing the MPSC to focus on the particular components if there is a concern. Another member expressed concern that as hospitals are consolidating under a single network more frequently for financial and administrative purposes, the proposed language may be too prescriptive in some regards and not prescriptive enough in others.

While members acknowledged that this proposal is intended to address safety concerns, defining buildings that are not structurally attached as geographically distinct, may have unintended consequences. The Committee was not able to endorse this proposal as written but recommended that in an effort to determine the impact on centers the MPSC survey the community.

3. Proposal to Implement Pre-Transplant Performance Review by the MPSC

The MPSC reviews transplant program performance. Currently, these reviews include only post-transplant patient and graft survival and transplant activity levels. Reviewing only post-transplant performance results in an unbalanced review of programs. Evidence that focusing only on post-transplant performance results in risk aversion and decreased transplant volumes which is not in the best interest of the patients on the waiting list. Pre-transplant performance review became a focus of the MPSC in the mid-2000s following a couple of high profile cases involving inadequate waiting list mismanagement.

The goal of the proposal is to create a tool to help the MPSC identify programs that are not meeting the needs of the patients on their waiting list. The tool would help the MPSC discover those programs that need improvement in waiting list management including increasing acceptance of deceased donor organ offers, transplanting patients on the waiting list and decreasing waiting list mortality. The establishment of a pre-transplant metric and trigger for review will allow for a more balanced overall view of a programs' performance through the spectrum of transplant care.

Another member noted that the CPM may be utilized as a predictive tool for centers to help them monitor themselves before ever encountering a formal issue with the MPSC. Some responded that while this may be intended as an internal tool for the centers, it could eventually become publically available information.

One member acknowledged that this proposal is one step forward in holding centers accountable for waitlist management but cautioned utilizing a complex formula that incorporates the DSA supply to demand ratio, which is widely variable. Another member added that DCD and ECD donors should also be incorporated into this model otherwise the community would miss an opportunity to improve that area of practice.

Members suggested that the MPSC review the organ acceptance rate and establish a CUSUM model to accompany the CPM. Overall the Committee was supportive of the idea of CPM as a tool for centers but cautioned the MPSC to consider the potential long term implications.

4. Proposal to Establish a Quality Assurance and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

A quality assurance process is a widely accepted tool for evaluating and implementing process and performance improvements in healthcare. The transplant community also recognizes the value of more thorough quality improvement initiatives. More specifically, the MPSC noted that members who are under review by the MPSC and are having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement programs. This problem has been observed during peer visits and in reviews of members with a significant non-compliance history or extended periods of underperformance.

Although CMS requires transplant hospitals and OPOs to have QAPI programs in place, the OPTN has no such requirement. So, the MPSC may request information about a member's QAPI processes and ask them to submit their plans for performance improvement, corrective action or quality improvement. However, the MPSC has no basis within OPTN policy or bylaws for requiring a member to implement or strengthen its QAPI program. The MPSC also cannot hold members accountable where the lack of an adequate QAPI program has resulted in a serious lapse in compliance or performance. In addition, not all transplant programs are CMS approved so CMS conditions of participation do not apply to those programs.

While developing this proposal, the MPSC reviewed the requirements of CMS and made sure that the proposal was consistent. The MPSC tried to reach a balance between a requirement that did not provide enough detail for members to know what was expected of them and a requirement that was too detailed and proscriptive. The MPSC included an obligation for the organization to develop a QAPI plan with enumerated broad components. The member is also required to implement that plan.

Several members voiced concern that this proposal was duplicative of the current CMS requirements and create an unnecessary burden for members. Members felt that if CMS approved a center the OPTN should honor the CMS certification.

Ultimately the Committee voted in support of the proposal, 92% in favor, 0% not in favor, 8% abstained, with the following amendment, "The OPTN established quality assurance and performance improvement requirements only apply to centers that are not CMS approved or certified."

5. Policy Rewrite Parking Lot "Quick Fixes"

In 2013 the Policy Oversight Committee (POC) sponsored the OPTN Policies Plain Language Rewrite, to clarify and increase policy readability and consistency, which became effective February 1, 2014. This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies. Many of the items in the parking lot came from OPTN members who responded during the rewrite's public comment period.

During the rewrite, reviewers identified a number of issues that would require substantive changes to the policies; these issues were recorded in the rewrite "parking lot" to be addressed in the future. Staff and OPTN/UNOS Committees identified the easy to fix changes that had been stored in the parking lot. Although the POC has identified

“easy” fixes, the parking lot still has a number of identified issues that the appropriate committees will address in separate projects. These projects will allow for input and collaboration with all the appropriate stakeholders. For example, the parking lot includes a number of comments and concerns about the deceased donor requirements in Policy 2, but these are being addressed as a separate project by the OPO Committee because they are too complex to include here. There are numerous items like this in the parking lot that are best addressed by the appropriate Committee, with input from the appropriate stakeholders. Their comments and concerns were discussed and addressed by staff and the POC before including them in this proposal.

Included in this proposal are several sections of liver specific policy where “should” would convert to “must.” Members of the Committee were generally supportive of the overall proposal but requested that the policies specific to any liver diagnosis such as hepatocellular carcinoma (HCC) or cholangiocarcinoma should be extracted so that the appropriate subcommittees could address these potential changes more in depth. Members were concerned over requiring what was initially intended as guidance.

Other Significant Items

6. Development of Regional Risk of Death Calculator

The Committee requested the SRTR develop a calculator to predict the 90-day risk of various waiting list outcomes (e.g., transplant, death, other removal, still waiting) by MELD/PELD score category, blood type, donor service area (DSA) and Region. The SRTR presented a beta version to the Committee. The calculations were based on historical data from a 2-year time period, so rather than being a predictive tool, the calculator displays what actually happened in the selected DSA or region. These data can be updated periodically to reflect more recent outcomes.

One member suggested that while this calculator may be a simple tool in general, there are other factors that should be considered, such as whether the patient has exception points that would influence their risk of transplant or death. Further, the member stated that there should be a detailed explanation for patients as to how these factors influence individual waiting list outcomes. Other members stated that this tool is not intended to give individual predictions, but rather an overall idea of the likelihood of transplant (or other outcome) given the range of MELD/PELD score and the location of the transplant center.

Members were impressed with the beta version, and urged the SRTR to explore whether MELD/PELD exceptions could be incorporated into the calculator.

Upcoming Meeting(s)

- The next Committee conference call will take place in December, 2014.