

Notice of OPTN Bylaw Changes

Enhance Transplant Program Performance Monitoring System, Phase 1 (July 2022)

Sponsoring Committee: Membership and Professional Standards
Bylaws Affected: *Appendix D, D.12.A. Transplant Program Performance*
Appendix L, L.3 Medical Peer Review
Appendix L, L.6 Peer Visits
Appendix L, L.9 Informal Discussions
Appendix L, L.15 Costs and Expenses
Appendix M: Definitions

Public Comment: *August 3, 2021 – September 30, 2021*

Board Approved: *December 6, 2021*

Effective Date: *July 14, 2022:*

Appendix D, D.12.A. Transplant Program Performance
except adult and pediatric criteria for pre-transplant
mortality rate ratio and offer acceptance rate ratio
Appendix L, L.3 Medical Peer Review
Appendix L, L.6 Peer Visits
Appendix L, L.9 Informal Discussions
Appendix L, L.15 Costs and Expenses
Appendix M: Definitions

Pending implementation and notice to OPTN members:
Appendix D, D.12.A. Transplant Program Performance
adult and pediatric criteria for pre-transplant mortality
rate ratio and offer acceptance rate ratio

Purpose of Bylaw Changes

Previously, the OPTN Membership and Professional Standards Committee (MPSC) has used a single metric that evaluates one phase of care, one-year post-transplant graft and patient survival, for identifying underperforming transplant programs. The MPSC recognized the need to incorporate metrics that evaluate multiple phases of transplant care to create a more holistic approach to evaluation of transplant program performance.

The purpose of this bylaw change is to evaluate transplant program performance more holistically, incorporating measures that evaluate multiple aspects of transplant patient care. In developing this new system, the MPSC focused on areas that were within the OPTN's stated authority. With this bylaw

change, the MPSC strived to support and collaborate with transplant programs to address performance improvement opportunities while also meeting its fiduciary responsibility to monitor member performance to identify potential patient safety issues. Finally, the MPSC wanted to develop a performance review system that would provide maximum support for the OPTN Strategic Plan, specifically increasing the number of transplants, promoting equitable access to transplantation, and fostering innovation.

Proposal History

The OPTN Ad Hoc Systems Performance Committee (SPC), in its report to the OPTN Board of Directors in June 2019, provided recommendations across four areas, including performance monitoring enhancements. The SPC stated a holistic approach to the evaluation of transplant hospital and OPO performance would be beneficial and suggested developing a balanced scorecard approach that incorporated multiple metrics. Although the SPC identified metrics for possible inclusion in a scorecard, the SPC acknowledged the need for more input and work to identify and define the appropriate metrics for scorecards. After the SPC report to the Board, the MPSC was asked to continue work on this topic.

The MPSC, over a 20-month period, evaluated the measures suggested by the SPC and MPSC members and gathered input from the community and stakeholders to develop a proposal that was released for public comment in summer 2021. The proposal identified a measure for each of four phases of pre- and post-transplant patient care provided by transplant programs and established separate adult and pediatric criteria to identify clinically significant outliers that may pose a potential risk to patient health or public safety. The Board approved these bylaw revisions on December 6, 2021.

Summary of Changes

The revised *OPTN Bylaw, Appendix D, D.12.A. Transplant Program Performance* establishes new criteria for identification of transplant programs that will enter into MPSC performance review. The MPSC will review a transplant program's performance if the transplant program meets the criteria for pre-transplant mortality rate, offer acceptance rate, 90-day post-transplant graft survival hazard ratio or 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival for either adult transplants or pediatric transplants. *OPTN Bylaw, Appendix D, D.12.A. Transplant Program Performance* is also re-organized to clarify but not substantively change, transplant program obligations to participate in the performance review process.

In addition, a new section is inserted in *Appendix L: Review and Actions* that codifies the current peer review process and corresponding revisions were made to other sections with *Appendix L: Reviews and Actions* that reference peer visits. Descriptions of the new metrics have been inserted into *Appendix M: Definitions* and other administrative revisions have been made to *Appendix M: Definitions* to remove the definitions of two defunct MPSC subcommittees and revise the definition of the Scientific Registry of Transplant Recipients (SRTR).

Implementation

On **July 14, 2022**, the MPSC will begin evaluating transplant programs based on the criteria for the new post-transplant metrics, 90-day post-transplant graft survival and 1-year post-transplant graft survival conditional on 90-day graft survival under the performance review process as provided in the revised *Appendix D.12.A. Transplant Program Performance*. The approved bylaw revisions *Appendix L: Reviews and Actions*, and *Appendix M: Definitions* will also be effective **July 14, 2022**.

The MPSC will send initial inquiries to transplant programs that meet the criteria for 90-day post-transplant graft survival and 1-year post-transplant graft survival conditional on 90-day graft survival in late July. Inquiries generally request information about a transplant program's structure and staffing, procedures and protocols, quality review processes, and plans for improvement. The MPSC will review the information submitted by the program and may request that the program submit additional information about certain aspects of the program or submit a plan for quality improvement. The MPSC may also request that a member participate in additional engagement with the MPSC, such as an informal discussion or a peer visit. In rare circumstances where the MPSC identifies a potential ongoing risk to patient health or public safety, the MPSC may request that a member inactivate or withdraw a transplant program or a component of a program to mitigate the risk.

The implementation of the two pre-transplant metrics will be phased on the following timeline:

- No earlier than July 2023: first inquiries for offer acceptance rate
- No earlier than July 2024: first inquiries for pre-transplant mortality rate

The OPTN will provide members with notice of pending implementation of the two pre-transplant metrics approximately 6 months prior to implementation.

Affected Bylaw Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

D.12 Additional Transplant Program Requirements

A. Transplant Program Performance

The MPSC will conduct reviews of transplant program performance to identify potential risks to patient health or public safety, as evidenced by either:

1. The probability that the transplant program meets any of the following criteria is greater than 50% for adult transplants:

- a. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year time period. For pancreas transplant programs, 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.
- b. The transplant program's 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival hazard ratio is greater than 1.75 during a 2.5 year period. For pancreas transplant programs, 1-year post-transplant patient survival conditional on 90-day post-transplant patient survival hazard ratio is greater than 1.75 during a 2.5 year period.

2. The probability that the transplant program meets any of the following criteria is greater than 50% for pediatric transplants:

- a. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.
- b. The transplant program's 1-year post-transplant graft survival conditional on 90 day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.

If a transplant program meets either of the above criteria based on reports produced by Scientific Registry of Transplant Recipients (SRTR), it must participate in an MPSC performance review. As part of the transplant program review, the MPSC may require the member to take appropriate actions to determine if the program has demonstrated sustainable improvement including, but not limited to:

- Providing information about the program structure, procedures, protocols and quality review processes
- Adopting and implementing a plan for improvement
- Participating in an informal discussion with MPSC members as described in *Appendix L: Reviews and Actions*
- Participating in a peer visit as described in *Appendix L: Reviews and Actions*

Once a member is under transplant program performance review, the MPSC will continue to review the program until the MPSC determines that the program has made sufficient and sustainable improvements in acting to avoid risk to public health or patient safety.

If the MPSC's review determines that a risk to patient health or public safety exists, the MPSC may request that a member inactivate or withdraw a designated transplant program, or a specific component of the program to mitigate the risk. Before the MPSC requests that a member inactivate or withdraw a designated transplant program or a specific component of the program due to concerns identified during a performance review, the MPSC must offer the member an informal discussion with the MPSC, as described in *Appendix L: Reviews and Actions*.

A member's failure to fully participate in the review process or to act to avoid a risk to patient health or public safety may result in action taken under *Appendix L: Reviews and Actions*.

underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC review will be to determine if the higher hazard ratio or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will be considered a noncompliance with OPTN Obligations and may result in an OPTN action according to *Appendix M: Reviews and Actions*.

As part of this process, the MPSC may conduct a peer visit to the program at the member's expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion will be conducted according to *Appendix M: Reviews and Actions*.

The MPSC may recommend that a member inactivate a program, or a component of a program, or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. The MPSC must offer the member an informal discussion before recommending that the program inactivate or withdraw its designated transplant program status. A program's failure to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so will be considered a

~~noncompliance with OPTN Obligations and may result in an OPTN action according to Appendix M: Reviews and Actions.~~

Appendix L: Reviews and Actions

L.3 Medical Peer Review

The OPTN will conduct all deliberations and take all actions according to applicable medical peer review laws. Consistent with applicable laws, all inquiries, peer visits, deliberations, recommendations, and actions during member reviews by the OPTN will be kept confidential. All proceedings and records within the scope of these OPTN quality review activities are confidential. Members of any OPTN Committee attending the meeting in which a peer review is conducted, serving as a peer reviewer, working for or on behalf of the OPTN, or providing information to the OPTN for peer review activities, are entitled to confidentiality.

The OPTN will keep all materials, information, and correspondences to and from members and directly related to the OPTN peer review process confidential to promote quality improvement and full disclosure by OPTN members. Materials, information, and correspondences created by or for the peer review body are considered “directly related.”

The OPTN will not disclose any materials provided to the OPTN by the member, except as required by law. Materials prepared by members independent of the OPTN medical peer review process may be shared by members in their discretion.

L.6 Peer Visits

A peer visit is an objective, on-site evaluation of a member by experienced transplant professionals. The MPSC or MPSC Chair may require a member under any MPSC review participate in a peer visit.

The MPSC Chair will appoint the peer visit panel. The peer visit panel will have access to all information available to the MPSC prior to the site visit. While on site, the peer visit panel will review records, interview staff and tour the facilities as desired. After the visit, the peer visit panel will prepare a report for the MPSC. The MPSC will review the report and determine the appropriate next steps.

A member’s refusal to participate in the peer visit in the time and format determined by the MPSC Chair, or a member’s refusal to provide requested information or to make available requested personnel, will be considered a potential noncompliance with OPTN Obligations.

L.89 Informal Discussions

An informal discussion is a direct conversation between a group of MPSC members and a member currently under MPSC review. Informal discussions are intended to provide the MPSC and member an opportunity to openly discuss the review and seek feedback. Informal discussions are information gathering activities that may lead to a more efficient and effective review than written correspondence and document reviews alone.

B. MPSC Informal Discussion Requests

The MPSC or MPSC Chair may offer members currently under review one or more informal discussions at any time. A transplant program is entitled to an informal discussion before the MPSC recommends that the program, or a component of the program, inactivate or withdraw its designated transplant program status due to functional inactivity or transplant program performance reviews according to *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*.

L.1415 Costs and Expenses

B. Reasonable Costs and Expenses

Reasonable costs and expenses resulting from enforcement of OPTN Obligations will be reimbursed by the member, including *any* of the following:

1. Conducting other than routine on-site reviews
2. Peer visits
3. Reviewing and monitoring corrective action plans or plans for quality improvement
4. Conducting due process proceedings
5. ~~Monitoring and conducting evaluations of transplant programs with lower than expected survival rates as described in Section D.12.A: Transplant Program Performance of these Bylaws, including on-site visits and monitoring plans for quality improvement~~

C. Advanced Deposit for Reimbursable Costs and Expenses

The Executive Director may require that the member make and maintain a deposit with the OPTN in an amount equal to the currently projected costs and expenses of any of the following:

1. OPTN on-site reviews
2. OPTN ~~member peer on-site reviews~~ peer visits
3. The interview
4. The hearing

Appendix M: Definitions

90-Day Post-Transplant Graft Survival Hazard Ratio

Measures graft survival from date of transplant to 90-days post-transplant relative to the expected 90-day post-transplant graft survival following risk adjustment for donor and recipient characteristics.

1-year Post-Transplant Graft Survival Conditional on 90-day Post-transplant Graft Survival Hazard Ratio

Measures graft survival from day 90 post-transplant to day 365 post-transplant, conditional on the graft surviving for the first 90-days post-transplant, relative to the expected graft survival following risk

adjustment for donor and recipient characteristics. The evaluation cohort excludes all transplants where the graft failed during the first 90-days post-transplant.

Offer Acceptance Rate Ratio

Measures a program's rate of accepting organ offers relative to the expected offer acceptance following risk adjustment for donor and candidate characteristics. Only offers for which the candidate was at some point the primary potential transplant recipient for the donor organ are evaluated.

Performance Analysis and Improvement Subcommittee (PAIS)

A subcommittee of the Membership and Professional Standards Committee charged with reviewing analyzing how a member's actual performance, including post-transplant survival rates and functional activity levels, compares with expected performance.

Policy Compliance Subcommittee (PCSC)

A subcommittee of the Membership and Professional Standard Committee charged with reviewing a member's compliance with OPTN rules and regulations.

Pre-Transplant Mortality Rate Ratio

Measures a program's rate of candidate mortality from a candidate's registration date and before any subsequent transplant relative to the expected mortality following risk adjustment for candidate characteristics at the time of registration. All candidates on the program's waiting list at any time during the measurement interval are included, and candidate deaths following removal from the waiting list for reasons other than transplant, transfer, or 60 days post-recovery during the measurement interval are included.

Scientific Registry of Transplant Recipients (SRTR)

The organization responsible for providing statistical and other analytic support to the OPTN. that provides ongoing evaluation of clinical data about donors, transplant candidates, and recipients, as well as patient and graft survival rates. The SRTR also provides analytic support to HHS in a variety of areas including: policy formulation and evaluation, system performance metrics, economic analysis, and preparation of recurring and special reports to Congress. The SRTR contract is awarded by HRSA, who oversees and funds it.