

Notice of OPTN Management and Membership Policy Change

Update Criteria for Post-Transplant Graft Survival Metrics

Sponsoring Committee:	Membership and Professional Standards (MPSC)
OPTN Management and Membership Policies¹ Affected:	<i>D.12.A Transplant Program Performance</i>
Public Comment:	September 17, 2024-October 16, 2024
Board Approved:	November 21, 2024
Effective Date:	March 6, 2025

Purpose of Policy Change

Remove barriers to increasing the number of transplants to support the Expeditious Task Force bold aim of 60,000 deceased donor transplants in 2026.

Proposal History

The Expeditious Task Force identified MPSC review of post-transplant graft survival as a potential barrier to bold aim of 60,000 deceased donor transplants in 2026 and requested that the MPSC consider suspension of review of post-transplant outcomes. The MPSC did not support suspension but expressed a willingness to consider changes to the thresholds for 90-day and 1-year conditional on 90-day graft survival that would identify less transplant programs. Following a request from the OPTN Executive Committee, the MPSC reviewed data on the number and characteristics of transplant programs that would be identified by alternative thresholds for 90-day and 1-year conditional on 90-day graft survival and the results of MPSC transplant program performance monitoring of transplant programs identified in July 2022. The MPSC proposed a new threshold that will encourage programs to perform more transplants by accepting more medically complex donor organs and potential candidates while also fulfilling the MPSC's charge to protect patient safety.

There was broad support for the proposed threshold change during public comment and the OPTN Board of Directors approved the policy changes on November 21, 2024.

¹ This proposal was originally drafted using the former structure of the OPTN Policies and OPTN Bylaws. On December 2, 2024, the OPTN adopted a new structure of governance, splitting the OPTN Bylaws into two documents: the OPTN Bylaws and OPTN Management and Membership Policies. The references to the affected provisions have been updated to match the format adopted in December. For more information, please see the OPTN proposal *Revised Bylaws and Management and Membership Policies*, available at https://optn.transplant.hrsa.gov/media/vwuovfyu/excom_revised-bylaws-and-management-and-membership-policies_bp.pdf.

Summary of Changes

The revised OPTN Management and Membership Policies, Appendix D, D.12.A. establishes new thresholds for flagging transplant programs for **adult** 90-day and 1-year conditional on 90-day graft survival to a greater than 50% probability that a program's hazard ratio is greater than 2.25 during a 2.5 year period. There is no change to the thresholds for 90-day and 1-year conditional graft survival for pediatric recipients or for the offer acceptance or pre-transplant mortality metrics. Transplant programs that are flagged under the new thresholds will receive an inquiry from the MPSC and enter MPSC transplant program performance monitoring.

Implementation

Transplant hospitals will need to become familiar with the proposed new thresholds for the 90-day and 1-year conditional on 90-day post-transplant graft survival metrics. Transplant hospital members should review the data currently available for each transplant program via the members' private SRTR site, to assess whether a program is likely to be identified for review once the proposal is implemented. Upon implementation of the new thresholds, the MPSC expects a significant decrease in the number of transplant programs flagged under these two metrics.

The proposed changes will not result in any change to the OPTN process of performance review but will result in a reduced number of programs entering that review process. The change to the flagging thresholds for the 90-day and 1-year conditional on 90-day graft survival metrics will be implemented on March 6, 2025, the last day of the Spring MPSC meeting after which inquiries to transplant programs will be sent.

Affected Management and Membership Policy Language²

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

D.12 Additional Transplant Program Requirements

A. Transplant Program Performance

Appendix D.12.A does not apply to VCA transplants.

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 pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
 - b. The transplant program's offer acceptance rate ratio is less than 0.30 during a 1 year

² This proposal was originally drafted using the former structure of the OPTN Policies and OPTN Bylaws. On December 2, 2024, the OPTN adopted a new structure of governance, splitting the OPTN Bylaws into two documents: the OPTN Bylaws and OPTN Management and Membership Policies. The references to the affected provisions have been updated to match the format adopted in December. For more information, please see the OPTN proposal *Revised Bylaws and Management and Membership Policies*, available at https://optn.transplant.hrsa.gov/media/vwuovfyu/excom_revised-bylaws-and-management-and-membership-policies_bp.pdf.

period.

- c. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than ~~1.75~~ 2.25 during a 2.5 year time period. For pancreas transplant programs, 90-day post-transplant patient survival hazard ratio is greater than ~~1.75~~ 2.25 during a 2.5 year period.
- d. 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~~ 2.25 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~~ 2.25 during a 2.5 year period.

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

- a. The transplant program's pre-transplant mortality rate ratio is greater than 1.75 during a 2 year period.
- b. The transplant program's offer acceptance rate ratio is less than 0.35 during a 1 year period.
- c. The transplant program's 90-day post-transplant graft survival hazard ratio is greater than 1.60 during a 2.5 year period.
- d. 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*.