ISHLT
A Society that Includes Basic Science, the Failing Heart, & Advanced Lung Disease

ISHLT Response to OPTN Update Criteria for Post-Transplant Graft Survival Metrics

The International Society for Heart and Lung Transplantation (ISHLT) appreciates the opportunity to provide feedback on the "Update Criteria for Post-Transplant Graft Survival Metrics" OPTN special public comment.

Because it has the potential to reduce administrative burden on heart and lung transplant programs, ISHLT strongly supports the proposal. ISHLT offers the following general comments:

1) Although achieving the "bold aim" of 60,000 transplants in 2026 is welcomed, it would be helpful if the OPTN would provide more granularity about what is needed to achieve that goal (e.g. increased utilization of difficult to place donors, decreased non-utilization of organs, increased access to transplants for underserved populations, increased resources for transplant programs and OPOs to accommodate increased volume) and the how this proposal fits into the broader set of steps the Expeditious project is undertaking. In addition, breaking down the aim in terms of anticipated increases by organ would be helpful for entities such as ISHLT.

2) The term "complex donor organ" is not clearly defined in the public comment document. We presume this means traditionally difficult to place donors or donors with a high likelihood of non-utilization, but it would be helpful to the community for a clearer definition to be provided.

3) ISHLT is interested in whether the MPSC has considered other strategies or incentives to increase institutional support of programs that might balance the potential loss of this perceived benefit of MPSC program review.

4) The document makes the important point that other entities' actions (including SRTR public reporting and insurance provider Center of Excellence programs) may limit the potential benefit of the proposed change. What steps will the MPSC, the OPTN or HRSA take to mitigate this concern?

5) The OPTN encourages process improvement by defining a "performance improvement zone" in addition to the requirements of official MPSC review. With the current hazard ratio threshold of 1.75, the performance improvement zone applies to those programs with hazard ratio greater than 1.5 but not greater than 1.75.

   If the MPSC continues to offer process improvement support to those programs with HR>1.5, we believe that raising the threshold for official review to 2.25 will maintain the importance of continuous process improvement while reducing the impact official MPSC review may have on acceptance of organs and transplant candidates.

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6) ISHLT remains concerned about the use of "special" public comment periods for issues that fall outside of the framework provided by the OPTN Bylaws. In our opinion, issues raised by this proposal are not sufficiently urgent to exclude the benefit in person / virtual presentation and discussion occurring during regional meetings provides to the process. ISHLT recommends that the OPTN Executive Committee develop a proposal to amend the OPTN Bylaws to include a framework for future proposals that don't meet existing criteria for off cycle public comment requests. At a minimum such a proposal should include criteria to justify off cycle timing, criteria for determining the length of the public comment period and a mechanism to allow members to request that the OPTN Board provide an opportunity for regional discussion of the proposal, either through regularly scheduled regional meetings or comparable events.

ISHLT Responses to the "Considerations for the Community"

Would a change to a threshold of 2.25 from 1.75 for 90-day and 1-year conditional on 90-day graft survival increase your willingness to accept more complex donor organs and perform more complex transplants?

Unlikely. As noted in the proposal and above there are many factors (both internal and external) that impact risk tolerance of transplant programs, including maintaining center of excellence status from third party payers. Moreover, we believe that most programs are mindful of their post-transplant survival while striving to achieve the common goal of getting the most possible patients transplanted with acceptable outcomes. In addition, smaller programs, where a single poor outcome has a disproportionately larger effect on performance metrics, may be less willing to adjust their practice based on this change. Thus, it is unlikely that this proposal alone will lead to a significant increase in utilization of difficult to place donors or donors with a high likelihood of non-utilization without addressing transplant center resource limitations and the oversight/impact of entities beyond the OPTN.

Do you support a change to the alternative threshold of 2.0 considered by the MPSC rather than the proposed 2.25 threshold?

Any reduction in the likelihood of being flagged for MPSC review would be welcomed by ISHLT and its members. ISHLT would welcome comment from the OPTN and HRSA regarding progress toward implementing NASEM report recommendation 13 ("Embed continuous quality improvement efforts across the fabric of the U.S. organ transplantation system") as an alternative to the current OPTN member quality program and recommendation 14 ("Align reimbursement and programs with desired behaviors and outcomes") which would have the potential to address the resource limitation issues noted above. We believe efforts toward adoption of the NASEM goals would support the 60,000 transplants goal as or more effectively than this proposal.

Would you support an increase in the threshold for the offer acceptance rate ratio to identify more programs and incentivize programs to accept more organs?

ISHLT supports the MPSC decision in the current proposal to leave the offer acceptance rate ratio threshold unchanged. ISHLT will **strongly oppose** increasing the threshold in the future unless multi-criteria offer filters for all organs are in place and data is available to support the assertion that increasing the threshold will improve utilization.

Should the change in threshold be applied to pediatric transplants in addition to adult transplants?

The rationale provided in the document for excluding pediatric programs from this change is incomplete. It would have been helpful for the MPSC to provide similar data about the number of programs flagged and their outcomes as well as the impact of raising the current thresholds on the number of programs flagged.

Given that the impact of flagging programs is no different (and may be more significant for typically smaller pediatric programs with limited resources), in the absence of such data, there is inadequate justification for excluding pediatric programs.

Are patients supportive of the change in threshold which aims to increase access to more complex organs?

ISHLT does not have a mechanism to directly answer this question.

ISHLT Level of Support: Strongly Support the Policy

OPTN

Public Comment Proposal

Update Criteria for Post-Transplant Graft Survival Metrics

OPTN Membership and Professional Standards (MPSC) Committee

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UNOS Member Quality

Contents

Update Criteria for Post-Transplant Graft Survival Metrics

Affected Bylaws: *D.13.A: Transplant Program Performance*
Sponsoring Committee: *Membership and Professional Standards (MPSC)*
Public Comment Period: *September 17, 2024 – October 16, 2024*

Executive Summary

The Expeditious Task Force has set a bold aim of 60,000 transplants in 2026. As part of its efforts to support reaching that bold aim, the Task Force evaluated OPTN policies and bylaws that may pose barriers to utilization and efficiency. MPSC review of post-transplant graft survival was identified as a potential barrier, based on the perception that the potential for MPSC review of transplant programs for post-transplant graft survival outcomes contributes to risk averse behavior. The MPSC did not support suspension of review of all post-transplant outcomes, citing concerns for patient safety and patient and public perception, and recognizing that MPSC review of programs can drive positive change that increases institutional support of programs. Potential alternative options were discussed that included consideration of changes to the flagging thresholds for review, risk adjustment model improvement, and additional educational efforts.[1] The OPTN Executive Committee requested that the MPSC consider adjusting the post-transplant outcomes metrics flagging threshold thereby removing a barrier to increased transplants by flagging fewer programs. The OPTN Executive Committee requested that the MPSC also consider adjusting the offer acceptance flagging threshold to capture more programs thereby creating a stronger incentive for transplant programs to accept more organs.

The MPSC proposes to change the flagging threshold for 90-day graft survival and 1-year conditional on 90-day graft survival for adult transplant recipients from a 50% probability that the transplant program's hazard ratio is greater than 1.75 (75% higher than expected) to a 50% probability that the transplant program's hazard ratio is greater than 2.25 (125% higher than expected). For the post-transplant graft survival metrics, a 1.0 hazard ratio indicates a transplant program is performing as expected taking into account the donor and recipient characteristics and a higher hazard ratio indicates a program is performing worse than expected. The MPSC noted that a threshold of 2.25 hazard ratio would continue to identify the transplant programs that have the greatest need for improvement and that the majority of serious patient safety issues are identified through other monitoring activities. This change to the threshold should reduce transplant program concern about potential MPSC performance monitoring and encourage transplant programs to accept and transplant more complex donor organs resulting in more candidates receiving a transplant faster. The MPSC decided not to change the offer acceptance rate ratio flagging threshold as there has not been sufficient time to evaluate the effect of review of transplant programs for offer acceptance since the metric's implementation in July 2023 and to provide an opportunity for further development of robust multi-criteria offer filters for all organs.

[1] January 19, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/2eqhmjlm/01192024_optn_mpsc_meeting-summary.pdf.

Purpose

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

Background

The MPSC developed a new transplant program performance monitoring system that is designed to evaluate transplant program performance more holistically by including pre-transplant metrics, rather than focusing solely on post-transplant outcomes. The proposal for this new system, which included two pre-transplant metrics, pre-transplant mortality rate ratio and offer acceptance rate ratio, and two post-transplant metrics, 90-day graft survival hazard ratio and 1-year conditional on 90-day graft survival hazard ratio, was approved by the OPTN Board of Directors in December 2021.[2] The new metrics have been implemented in phases. As programs had previous experience being reviewed for post-transplant patient and graft survival, the two post-transplant graft survival metrics were implemented in July 2022. The offer acceptance rate ratio was implemented in July 2023. The MPSC delayed implementation because the July 2023 Scientific Registry of Transplant Recipients (SRTR) MPSC data reports were the first biannual SRTR report to evaluate offer acceptance using a full cohort of offers (January 1, 2022 – December 31, 2022) following approval of the MPSC proposal by the OPTN Board of Directors. Finally, the last metric, pre-transplant morality rate ratio, was implemented in July 2024. The July 2024 SRTR MPSC data reports were the first SRTR report to evaluate pre-transplant mortality based on an observation period (January 1, 2022 – December 31, 2023) that followed approval of the MPSC proposal. The new transplant program performance monitoring system produced about the same number of flags as the previous system that focused solely on post-transplant patient and graft survival, resulting in approximately a 50% reduction in the number of flags under the two post-transplant graft survival metrics.[3]

The Expeditious Task Force has set a bold aim of 60,000 transplants in 2026. As part of its efforts to support reaching that bold aim, Expeditious evaluated OPTN policies and bylaws that may pose barriers to utilization and efficiency. MPSC review of post-transplant graft survival was identified as a potential barrier, based on the perception that the potential for MPSC review of post-transplant graft survival contributes to risk averse behavior by transplant programs. Expeditious initially requested that the MPSC consider a moratorium on review of transplant programs' post-transplant graft survival.

The MPSC reviewed data showing that, in January 2024, 38 out of 718 programs or 5% of programs were under review by the MPSC for either 90-day post-transplant graft survival or 1-year conditional on 90-day post-transplant graft survival. The biggest outliers for adult transplants had hazard ratios around 3.0, or three times the number of graft failures as expected after risk adjustment. The MPSC did not support suspension of review of all post-transplant outcomes, citing concerns for patient safety and patient and public perception, and recognizing that MPSC review of programs can drive positive change that increases institutional support of programs. The MPSC also noted that even if it suspended all post-transplant outcome review, there are other entities (e.g., SRTR public reporting, insurance provider Center of Excellence criteria) that would continue to assess post-transplant metrics. Potential alternative

[2] MPSC Briefing to the OPTN Board of Directors on Enhance Transplant Program Monitoring System, December 6, 2021. Available at https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf.
[3] MPSC Report to the Board of Directors, November 29, 2023. Report available at https://optn.transplant.hrsa.gov/media/i11oj3v5/20231129_mpsc_report-to-the-board.pdf.

options were discussed that included consideration of changes to the flagging thresholds for review, risk adjustment model improvement, and additional educational efforts.[4] The OPTN Executive Committee then passed a resolution requesting that the MPSC consider revising the flagging thresholds for the two post-transplant outcomes metrics and for the offer acceptance metric. In the resolution, the OPTN Executive Committee requested that the MPSC consider adjusting the post-transplant outcomes metrics flagging threshold thereby removing a barrier to increased transplants by flagging fewer programs. The OPTN Executive Committee requested that the MPSC also consider adjusting the offer acceptance flagging threshold to capture more programs thereby creating a stronger incentive for transplant programs to accept more organs. Following this resolution, the MPSC agreed to consider changes to the flagging thresholds for both of the post-transplant graft survival metrics and the offer acceptance metric for adult candidates and transplants.[5]

Overview of Proposal

The MPSC proposes to change the threshold for adult 90-day graft survival and 1-year conditional on 90-day graft survival for adult transplant recipients from a 50% probability that the transplant program's hazard ratio is greater than 1.75 (75% higher than expected) to a 50% probability that the transplant program's hazard ratio is greater than 2.25 (125% higher than expected). The MPSC decided to change the threshold for these two metrics for adult recipients and not make a change to the thresholds for pediatric transplant recipients. The MPSC decided not to change the offer acceptance rate ratio threshold as there has not been sufficient time to evaluate the effect of review of transplant programs for offer acceptance since implementation of the metric in July 2023.

Post-Transplant Graft Survival Metrics Threshold

To determine the appropriateness of a change to the flagging threshold for the 90-day and 1-year conditional on 90-day graft survival metrics, the MPSC balanced its charge to protect patient safety and support members' improvement efforts with OPTN efforts to reduce barriers to transplants. The MPSC considered its extensive experience reviewing transplant programs for post-transplant outcomes; a literature review to determine if there is evidence that the potential for MPSC review of post-transplant outcomes results in risk-averse behavior by transplant programs; data on the hazard ratios of programs identified for review and the course of the review of those programs since the implementation of the current post-transplant outcome metrics in July 2022; and information on the number and data for programs that would or would not be flagged under different thresholds for 90-day and 1-year conditional on 90-day graft survival rate ratio.

The MPSC reviewed the findings of a review of literature from the last five years which located nine relevant articles. The majority of the articles were published prior to approval of the performance monitoring enhancement proposal. The search did not uncover definitive evidence of risk-averse behavior by transplant programs caused by concern that accepting more complex organs or performing more complex transplants could result in being flagged for MPSC post-transplant outcomes performance review. Importantly, one article from the United Kingdom noted the lack of studies examining decision making with risk in transplantation while acknowledging that the pressure to achieve regulatory

[4] January 19, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/2eqhmjlm/01192024_optn_mpsc_meeting-summary.pdf.
[5] April 23, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/ugvhawfe/20240423_mpsc_meeting-summary_public.pdf.

outcome benchmarks creates bias in accepting transplant risk.[6] Some articles referenced the perception that the sole focus of review on post-transplant outcomes and the thresholds at that time resulted in risk averse behavior and suggested the thresholds should be more lenient and other metrics should be included in review.[7] Other articles noted that volumes and acuity data and a survey of transplant professionals did not support community concerns regarding risk aversion related to Program Specific Report (PSR) utilization and regulatory metrics.[8] Finally, two articles that examined the effect of the OPTN Collaborative Innovation and Improvement Network (COIIN) project and included consideration of COIIN participation in MPSC reviews and an MPSC operational rule that removed higher risk transplants based on high Kidney Donor Profile Index (KDPI) into high Estimated Post-Transplant Survival (EPTS) recipients found that neither seemed to notably affect offer acceptance, kidney yield, or waitlist mortality rates.[9] The literature does not clearly support that the potential for MPSC post-transplant outcomes review results in risk-averse behavior. However, the perception that programs consider the potential of future MPSC review when determining whether to accept more complex organs or perform more complex transplants could pose a barrier to both increasing transplants and the resulting benefits of decreasing candidate waiting time and death on the waiting list.

Using the SRTR January 2024 PSR data, the MPSC examined the effect of a change in flagging thresholds for the two post-transplant graft survival metrics from 1.75 to 2.0 or to 2.25 on the number of programs flagged. Those results can be found in Table 1 below.

Table 1: Number of Flags for Different Adult Post-Transplant Graft Survival Metrics Thresholds

MPSC Metric	Current (1.75)	Alternate 1 (2.0)	Alternate 2 (2.25)
90-day post-transplant graft survival	25	13	12
1-year conditional on 90-day post-transplant graft survival	17	9	2
Total	42	22	14

[6] Sharif A. Risk Aversion, Organ Utilization and Changing Behavior. Transplant international. 2022;35:10339-10339. doi:10.3389/ti.2022.10339

[7] Kobashigawa JA, Hall S, Farr M, et al. Proceedings from the metrics forum in heart transplantation for performance monitoring. American journal of transplantation. 2022;22(5):1299-1306. doi:10.1111/ajt.16901; Shepherd S, Formica RN. Improving Transplant Program Performance Monitoring. Current transplantation reports. 2021;8(4):293-300. doi:10.1007/s40472-021-00344-z; Malamon JS, Ho B, Jackson WE, et al. An evaluation of the organ procurement and transplantation network's expanded post-transplant performance metrics. Frontiers in transplantation. 2023;2. doi:10.3389/frtra.2023.1237112

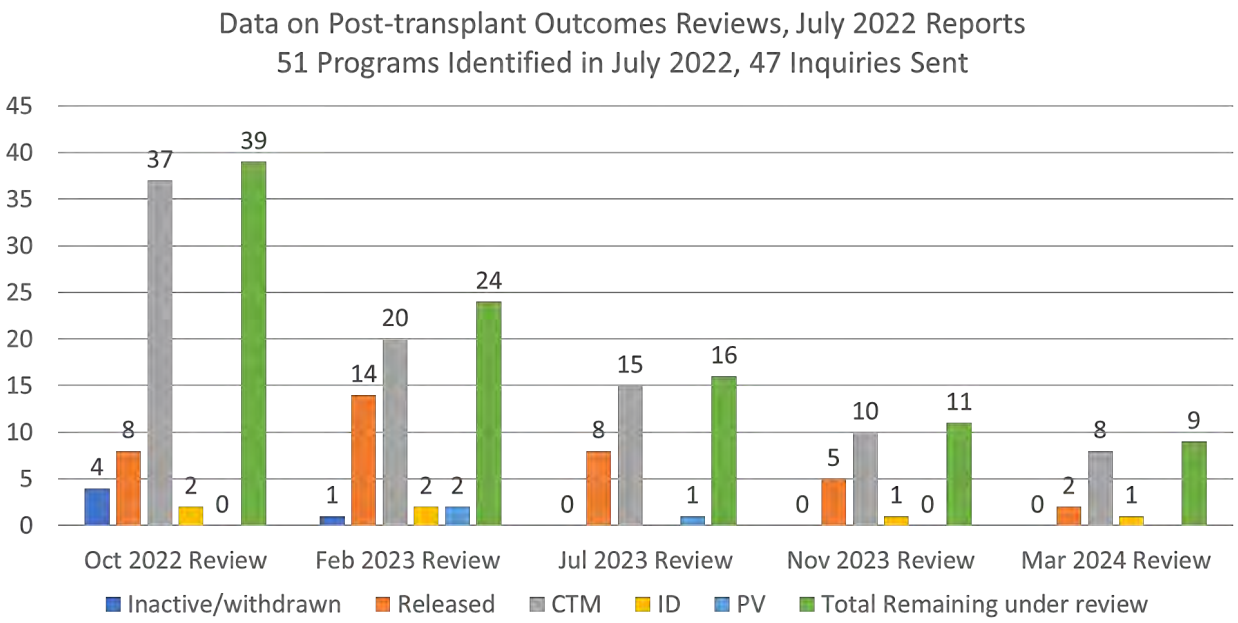
[8] Mikolajczyk AE, Rao VL, Diaz GC, Renz JF. Can reporting more lead to less? The role of metrics in assessing liver transplant program performance. Clinical transplantation. 2019;33(1):e13385-n/a. doi:10.1111/ctr.13385; Van Pilsum Rasmussen SE, Zhou S, Thomas AG, Segev DL, Nicholas LH. Transplant community perceptions of the benefits and drawbacks of alternative quality metrics for regulation. Clinical transplantation. 2019;33(4):e13500-n/a. doi:10.1111/ctr.13500

[9] Wey A, Foutz J, Gustafson SK, et al. The Collaborative Innovation and Improvement Network (COIIN): Effect on donor yield, waitlist mortality, transplant rates, and offer acceptance. American journal of transplantation. 2020;20(4):1076-1086. doi:10.1111/ajt.15657; Wey A, Salkowski N, Carrico RJ, et al. Association between changes in Membership and Professional Standards Committee review criteria and use of higher-risk kidneys for transplant. Clinical transplantation. 2020;34(7):e13872-n/a. doi:10.1111/ctr.13872

A change to a 2.0 threshold would result in a decrease from 42 adult flags to 22 adult flags with program hazard ratios between 2.03 – 2.99 in the January 2024 MPSC reports and a change to a threshold of 2.25 would further decrease the adult flags to 14 with program hazard ratios between 2.31 – 2.99.

The MPSC also reviewed data on the outcomes of reviews of the 47 programs that received initial inquiries for 90-day and 1-year conditional on 90-day graft survival in July 2022. There are three MPSC performance review cycles per year that coincide with MPSC multi-day meetings. Immediately following a flag, the transplant program receives an initial inquiry and is asked to complete a questionnaire and submit supporting documentation. It is not unusual for transplant programs that are participating in a MPSC performance review to remain under review for longer than the initial cycle, as often the MPSC reviewers will provide feedback and request additional information and clarification following the initial review. The available actions for transplant programs interacting with the MPSC based on performance are release from review, continue to monitor, informal discussion (ID), peer visit (PV), and very rarely, a request to inactivate. Length of time under review and requests for informal discussions, peer visits, or to inactivate a program can be indicators of the level of concern MPSC reviewers have about a program. There have been five review cycles since the 47 programs flagged in July 2022 received an initial inquiry. **Figure 1** below provides data on the actions taken over the five cycles. Fifty-one programs were flagged. Four of those programs were either inactive or withdrawn (dark blue bar in October 2022) at the time of flagging and did not receive an inquiry, so 47 initial inquiries were sent. **Figure 1** only includes the fifty-one programs flagged in July of 2022, and does not include information for additional programs that were flagged in later cycles, so does not represent all MPSC action taken for each cycle.

Figure 1: Post-Transplant Outcomes Reviews



The figure shows that after reviewing the transplant programs' initial submissions in October 2022, the MPSC released 8 transplant programs (orange bar), continued to monitor 27 programs (grey bar), and requested that 2 programs participate in an informal discussion (yellow bar), resulting in 39 programs remaining under review. Programs generally are released from review because the MPSC reviewers did not have significant concerns or, most likely, the program has a good quality system that identified the

concerns early and implemented an effective plan for improvement. At the end of one year of reviews (Nov 2023), 11 programs or about 23% of the programs that received an initial inquiry remained under review. Taking a deeper dive into those 11 program performance reviews, four had participated in an informal discussion prior to November 2023 and 2 more participated in an informal discussion over the next two cycles. Three of those programs had participated in a peer visit. The MPSC further evaluated data on whether those 11 programs that continued under review after 1 year would have been identified for review based on either a 2.0 hazard ratio or 2.25 hazard ratio threshold. Using a 2.0 hazard ratio threshold, all but one of these programs would have been flagged either in that same July 2022 SRTR MPSC report or the January 2023 or July 2023 SRTR MPSC reports. Using a 2.25 hazard ratio threshold, 4 of the 11 programs would not be flagged in the July 2022 SRTR MPSC reports or in any of the three SRTR MPSC reports (1/2023, 7/2023 or 1/2024) since July 2022. All three of the programs that participated in a peer visit would have been flagged under a 2.25 hazard ratio threshold either in July 2022 or one SRTR MPSC report later in January 2023. Two of the six programs that participated in an informal discussion would not have been flagged under a 2.25 hazard ratio threshold in the July 2022 SRTR MPSC reports or in any of the three SRTR MPSC reports (1/2023, 7/2023 or 1/2024) since July 2022.

The MPSC briefly discussed whether it is possible to conduct reviews using more recent data, as currently review is retrospective and based on data from one year prior to the review date, to allow for more agile MPSC responses to the sudden development of concerning transplant program behavior. SRTR staff informed the MPSC that current time frames are based on balancing quality and currency of data. There are monthly cumulative sum control charts (CUSUMs) available to transplant programs that provide data on how the program is trending for post-transplant outcomes. Potential MPSC review of these reports would require detailed investigation and consideration, as the data in CUSUMs is less reliable due to the lag between occurrence of reportable events and reporting of events. Another potential future option is utilizing a two-year prevalent window, which is a data reporting methodology already under investigation by the SRTR.

Following review of the data, the MPSC expressed support for changing the threshold to 2.25 by a vote of 19 in favor of 2.25 and 7 in favor of 2.0, noting that the vast majority of programs with serious patient safety issues were not identified through review of post-transplant outcomes, but rather through avenues such as patient safety reports, which will not be affected by a change in the flagging thresholds. MPSC members noted that monitoring of post-transplant outcomes is important for a holistic evaluation of transplant programs and that flagging for 90-day graft survival is typically a more reliable indicator of surgical problems, rather than 1-year survival conditional upon 90-day, and that based on the data presented, there are marginal changes between a 2.0 and a 2.25 threshold to the 90-day survival flag counts. The MPSC concluded that a threshold of 2.25 hazard ratio would continue to identify the transplant programs that have the most need for improvement and that the majority of serious patient safety issues are identified through other monitoring activities.[10] Adjusting the threshold may reduce transplant program concern about potential MPSC performance monitoring and encourage transplant programs to accept and transplant more complex donor organs resulting in more candidates receiving a transplant faster, which aligns with the Expeditious Task Force's initiatives. Many transplant programs transplant these more complex donor organs successfully.

[10] June 28, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/zkggzd0a/20240628_mpsc_meeting_summary.pdf.

The MPSC decided not to propose a change to the thresholds for 90-day and 1-year conditional on 90-day post-transplant graft survival for pediatric transplant recipients.[11] When developing the different thresholds for adult and pediatric post-transplant graft survival in the MPSC's December 2021 proposal[12], the MPSC recognized the need for closer monitoring of the transplant outcomes for children based on public perception and developed separate lower thresholds for post-transplant graft survival for pediatric transplants. Additional factors that influenced the development of a lower threshold included the smaller number of programs and low volume of pediatric transplants which makes it harder to determine statistically meaningful outliers. The purpose for this proposal for a change to the post-transplant graft survival metric thresholds is to decrease risk-averse behavior and encourage transplant programs to increase transplants through the acceptance of more complex donor organs and the performance of more complex transplants. The MPSC did not support changes to the thresholds for pediatric transplants for the same reasons cited for a lower pediatric threshold. Pediatric transplant program representatives noted that there are additional important considerations supporting avoidance of more complex donor organs for use in transplants in children, and therefore, changes to the metric thresholds should not be made to encourage use of these organs in pediatric recipients. Therefore, the MPSC proposes that the change to the 90-day and 1-year conditional on 90-day post-transplant graft survival metric thresholds only be applied to adult transplants at this time.

Offer Acceptance Metric Threshold

The MPSC evaluated a potential change to the adult offer acceptance threshold from a 50% probability that the transplant program's offer acceptance rate ratio is less than 0.30 to an offer acceptance rate ratio that is less than 0.35. For the offer acceptance metric, a 1.0 hazard ratio indicates a transplant program is performing as expected taking into account donor and candidate characteristics and a lower hazard ratio indicates a program is performing worse than expected. Using the January 2024 SRTR PSR data, a change to a threshold of 0.35 would increase the number of flags for offer acceptance for adult candidates from 23 to 32. If the MPSC increased the threshold to 0.40, the number of flags would increase to 49.

The MPSC recently began evaluating transplant programs' offer acceptance practices in July 2023. The MPSC's goal in evaluating programs based on this metric is to increase the number of transplants by encouraging the acceptance of more organs and the use of realistic donor acceptance criteria and offer filters, which allows for more complex donor organs to be allocated faster to those programs both willing to accept and possessing the resources to transplant and care for more complex transplant patients.

The initial set of inquiries were sent to programs flagged for offer acceptance following the July 2023 MPSC meeting and the MPSC reviewed transplant program submissions for the first time just prior to and at its November 2023 meeting. The MPSC did not require a submission from the flagged programs for the March 2024 review cycle and instead granted additional time for programs to further implement performance improvement plans and demonstrate improvement. The MPSC reviewed the programs' second submissions during its July 2024 in-person meeting. Therefore, when the MPSC considered in May and June 2024 whether to change the threshold, the MPSC had fully reviewed only one set of

[11] April 23, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/ugvhawfe/20240423_mpsc_meeting-summary_public.pdf.

[12] MPSC Briefing to the OPTN Board of Directors on Enhance Transplant Program Monitoring System, December 6, 2021. Available at https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf.

submissions from transplant programs flagged for offer acceptance. In contrast to decades of MPSC interaction with transplant programs based on post-transplant outcomes, the MPSC does not yet have sufficient experience reviewing programs flagged for offer acceptance to evaluate the need for a stricter flagging threshold. Therefore, the MPSC concluded that consideration of offer acceptance threshold changes at this moment is premature.

MPSC members commented on the positive impact of offer filters on kidney offer acceptance due to the robust filter options available, noting that the filters that have been released for other organs could have the same positive impact once the filter options are expanded. The multi-criteria offer filters help programs improve their offer acceptance rate ratio by allowing programs to exclude offers for organs that a program is unlikely to accept, thereby reducing the total offers received by the program and allowing more complex organs to be allocated expediently to transplant programs willing and able to use those organs. Multi-criteria offer filters have been available to kidney transplant programs since February 2022 and multi-criteria offer filters for other organs have been released more recently in February 2024 for lung and June 2024 for heart and liver. The MPSC concluded that, in addition to the limited MPSC experience reviewing transplant programs for offer acceptance, consideration of changes to the offer acceptance thresholds should be delayed, allowing for transplant programs to become more familiar with and evaluate the use of offer filters and for more criteria to be incorporated into the offer filters for heart, lung, and liver.[13]

NOTA and Final Rule Analysis

The Committee submits the following proposal under the authority of the OPTN Final Rule, which states "[t]he OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of: . . . (iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies."[14] One component of the OPTN's ongoing and periodic reviews and evaluations of OPOs and transplant hospitals is performance monitoring. This responsibility is further defined by the *OPTN Contract Task 3.6 OPTN member compliance and performance monitoring, quality improvement, and sanctioning,* which states:

> The Contractor shall monitor OPTN member performance, including threats to patient health and public safety, maintain and develop efforts to improve OPTN member performance, and impose sanctions when warranted.
>
> The Contractor shall develop processes to:
> - monitor and review OPTN member performance, including threats to patient health and public safety;
> - evaluate, assess, and monitor over time all OPTN members for compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws and policies;
> - educate and encourage OPTN member compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies; and
> - Promote member performance improvement to meet OPTN strategic planning goals as identified in Task 3.2.7.

[13] June 28, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/zkggzd0a/20240628_mpsc_meeting_summary.pdf.
[14] 42 C.F.R. §121.10 (b)(1)(iii)

The Contractor shall ensure that these processes encourage member self-reporting of potential compliance problems and provide incentives to report issues by assisting members in identifying root causes of issues and developing appropriate corrective actions.

In the event OPTN members are unable to increase compliance, improve performance, or mitigate threats to patient health or public safety, or unless otherwise determined to be appropriate, the Contractor shall develop processes consistent with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies to:

- impose OPTN sanctions as determined by the OPTN MPSC and [Board of Directors] BOD; and
- refer members to the Secretary when federal sanctions may be warranted.[15]

Performance monitoring is the OPTN's approach to identifying OPOs and transplant programs that are not performing according to key metrics that may implicate a patient safety concern. The MPSC has determined that the proposed change to the adult flagging threshold for the 90-day and 1-year conditional on 90-day post-transplant graft survival metrics will continue to identify outliers that are more likely to raise a potential patient safety concern while also potentially increasing transplants by reducing transplant program concerns about MPSC review for post-transplant outcomes.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

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 member's 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.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Operations affecting the OPTN

The proposed change to the flagging thresholds for the 90-day and 1-year conditional on 90-day graft survival metrics will be implemented in January 2025 to coincide with the release of the SRTR Fall 2024 program specific reports (PSR). 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.

[15] Organ Procurement and Transplantation Network; HHSH250201900001C. April 1, 2019.

Projected Fiscal Impact

Overall Projected Fiscal Impact

The Fiscal Impact Advisory Group reviewed this proposal and completed a survey to estimate anticipated costs. They rated this project as low, medium, or high based on the estimated staffing and/or training, overtime, equipment, or IT support needed in the implementation of this proposal. The proposal was determined to have a low overall fiscal impact on the organ procurement organizations and transplant hospitals. No fiscal impact was recorded for histocompatibility labs.

Projected Impact on the OPTN

It is estimated that $38,644 would be needed to implement this proposal. Implementation will include integration of new membership work processes, member communication through emails and news items, and web updates and publications of news items. It is estimated that $12,608 will be required for ongoing support. Ongoing support includes member support as well as creation of monitoring reports, news items, and website updates.

Projected Fiscal Impact on Organ Procurement Organizations

A low financial impact was found for OPOs. A potential positive fiscal impact included a possible increase in transplanted organs.

Projected Fiscal Impact on Transplant Hospitals

This proposal was said to have a low fiscal impact on transplant hospitals. Some members stated that there may be additional staff needed to fulfill the continued application of this proposal, or current staff may be needed for more hours to carry out tasks. Educating transplant hospital staff on this proposal was said to be relatively fast, with an estimated 1-2 hours for training. A potential impact of this proposal is that larger transplant programs could receive more funding as a result, which was noted in the project proposal.

Projected Fiscal Impact on Histocompatibility Laboratories

This proposal was said to have low to no fiscal impact on histocompatibility labs.

Post-implementation Monitoring

Member Compliance

While the criteria for 90-day and 1-year conditional on 90-day post-transplant graft survival used to identify transplant programs for MPSC engagement would change under this proposal, the review and engagement process will not substantially change. The proposed change in criteria will result in a smaller number of transplant programs flagged for 90-day and 1-year conditional on 90-day post-transplant graft survival. The OPTN will continue to receive reports from the SRTR twice a year that assess each transplant program's performance based on the criteria and will use these reports to identify transplant programs for MPSC engagement. The MPSC will continue to send inquiries to a

transplant program identified for engagement in order to request information about the program, such as:

- Program structure
- Procedures and protocols
- Quality review processes
- Plans for improvement

The MPSC will continue to review the information submitted by the program and may request that the member 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.

Bylaw Evaluation

The bylaw will be formally evaluated at least annually post-implementation. The MPSC will evaluate the effectiveness of the proposal through review of the number of transplants, post-transplant outcomes, and offer acceptance rates overall and by donor complexity, if possible. In order to evaluate any unintended consequences, the MPSC will also evaluate changes in the number of post-transplant graft failures and deaths.

Conclusion

The Expeditious Task Force has set a bold aim of 60,000 transplants in 2026. As part of its efforts to support reaching that bold aim, the Task Force evaluated OPTN policies and bylaws that may pose barriers to utilization and efficiency and identified MPSC review of post-transplant graft survival as a potential barrier based on the perception that the potential for MPSC review of post-transplant graft survival contributes to risk averse behavior by transplant programs. The MPSC did not support suspension of review of all post-transplant outcomes, citing concerns for patient safety and patient and public perception, and recognizing that MPSC review of programs can drive positive change that increases program institutional support. Potential alternative options were discussed that included consideration of changes to the thresholds for review, risk adjustment model improvement, and additional educational efforts.[16] Following a resolution by the OPTN Executive Committee requesting that the MPSC consider adjusting the flagging thresholds for the two post-transplant outcomes metrics to remove a barrier to increased transplants and for the offer acceptance metric to create a stronger incentive to accept more organs, the MPSC agreed to consider changes to the flagging thresholds for both of the post-transplant graft survival metrics and the offer acceptance metric for adult candidates and transplants.[17]

The MPSC proposes to change the flagging threshold for 90-day graft survival and 1-year conditional on 90-day graft survival for adult transplant recipients from a 50% probability that the transplant program's

[16] January 19, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/2eqhmjlm/01192024_optn_mpsc_meeting-summary.pdf.
[17] April 23, 2024, MPSC meeting. Meeting summary available at https://optn.transplant.hrsa.gov/media/ugvhawfe/20240423_mpsc_meeting-summary_public.pdf.

hazard ratio is greater than 1.75 (75% higher than expected) to a 50% probability that the transplant program's hazard ratio is greater than 2.25 (125% higher than expected). The MPSC noted that a threshold of 2.25 hazard ratio would continue to identify the transplant programs that have the greatest need for improvement and that the majority of serious patient safety issues are identified through other monitoring activities. Adjusting the threshold may reduce transplant program concern about potential MPSC performance monitoring and encourage transplant programs to accept and transplant more complex donor organs resulting in more candidates receiving a transplant faster, which aligns with the Expeditious Task Force's initiatives. The MPSC decided not to change the offer acceptance rate ratio threshold as there has not been sufficient time to evaluate the effect of review of transplant programs for offer acceptance since the metric's implementation in July 2023, and to provide an opportunity for further development of robust multi-criteria offer filters for all organs.

Considerations for the Community

The Committee encourages all interested individuals to comment on the proposal in its entirety, but specifically asks for feedback on the following:

- Would a change to a threshold of 2.25 from 1.75 for 90-day and 1-year conditional on 90-day graft survival increase your willingness to accept more complex donor organs and perform more complex transplants?
- Do you support a change to the alternative threshold of 2.0 considered by the MPSC rather than the proposed 2.25 threshold?
- Would you support an increase in the threshold for the offer acceptance rate ratio to identify more programs and incentivize programs to accept more organs?
- Should the change in threshold be applied to pediatric transplants in addition to adult transplants?
- Are patients supportive of the change in threshold which aims to increase access to more complex organs?

Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

D.13 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 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 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~~ 2.25during 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 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 M: Reviews and Actions*
- Participating in a peer visit as described in *Appendix M: 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 M: 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 M: Reviews and Actions*.

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