OPTN

Briefing to the OPTN Board of Directors on

Enhance Transplant Program Performance Monitoring System

OPTN Membership and Professional Standards Committee

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Contents

Executive Summary	2
Purpose	3
Background	3
Proposal for Board Consideration	4
Overall Sentiment from Public Comment	31
Compliance Analysis	33
Implementation Considerations	35
Post-implementation Monitoring	37
Conclusion	39
Bylaws Language	41
Appendix A	46

Enhance Transplant Program Performance Monitoring System

Affected Bylaws:	*Appendix D, D.13.A. Transplant Program Performance* *Appendix M, M.3 Medical Peer Review* *Appendix M, M.6 Peer Visits* *Appendix M, M.9 Informal Discussions* *Appendix M, M.15 Costs and Expenses* *Appendix N: Definitions*
Sponsoring Committee:	*Membership and Professional Standards*
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Executive Summary

The Membership and Professional Standards Committee (MPSC) conducts transplant program performance reviews under the authority of the Organ Procurement and Transplantation Network (OPTN) Final Rule §121.10 (b)(1)(iii) that requires that the OPTN establish plans and procedures for conducting ongoing and periodic reviews and evaluations of transplant hospitals for compliance with the Final Rule and OPTN bylaws and policies. This responsibility is further defined by the OPTN contract with the Health Resources & Services Administration (HRSA), which requires the contractor to "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."

Currently, the MPSC uses a single metric, one-year post-transplant graft and patient survival, for identifying underperforming transplant programs. The MPSC recognizes 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 MPSC proposal seeks to modify the OPTN Bylaws, Appendix D.13.A. *Transplant Program Performance*. Specifically, the proposal identifies new metrics, which evaluate both pre-and post-transplant aspects of patient care that the MPSC will use to assess transplant program performance to ensure these programs are performing safely. The proposal also establishes which transplant programs must participate in performance reviews by setting specific boundaries for each metric. Following public comment, the MPSC proposes the replacement of the term used for one of the proposed metrics, "waitlist mortality," with "pre-transplant mortality" due to a change in the term used for this metric by the Scientific Registry of Transplant Recipients (SRTR). The MPSC has also inserted descriptions of the proposed metrics in Appendix N: *Definitions* post-public comment. These changes will ensure consistency and transparency to the community regarding the metric that is being used to evaluate transplant programs. The proposal re-organizes and clarifies, but does not substantively change, transplant program obligations to participate in the performance review process. In addition, the proposal includes a new section in Appendix M: *Review and Actions* that codifies the current peer review process. Other administrative changes have been made to Appendix M: *Reviews and Actions* and Appendix N: *Definitions*. The MPSC asserts that this proposal improves upon the current performance evaluation system using reliable, available metrics that measure multiple aspects of transplant program patient care to create a better, more holistic transplant program performance monitoring system.

Purpose

In determining the specific goals of the project, the MPSC reviewed the OPTN's responsibilities regarding member reviews and evaluations under the OPTN Final Rule, the OPTN contract, and the MPSC charge[1]. The MPSC also considered the mission, vision, and goals within the 2018-2021 OPTN Strategic Plan[2]; and themes and recommendations described in the Ad Hoc Systems Performance Committee (SPC) report to the OPTN Board of Directors.

During its discussions, the MPSC acknowledged a few key goals that would shape the project. First, the MPSC understood that any proposal must be within the OPTN and MPSC's authority. There are many possible approaches to performance monitoring and metrics to consider; however, the MPSC must focus on areas clearly within the stated authority, which is addressed in subsequent sections of this briefing paper. Second, the MPSC acknowledged it has a fiduciary responsibility to monitor member performance to identify potential patient safety issues. At the same time, the MPSC strives to support and collaborate with transplant programs to address performance improvement opportunities. The MPSC also 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. The MPSC agreed that the proposal should develop a holistic review of member performance throughout all phases of transplantation. Finally, the MPSC acknowledged the need to improve the current performance review process, and committed to completing a proposal in a timely fashion.

The MPSC also recognizes that this proposal is the first step in moving beyond a singular focus on one-year post-transplant outcomes to evaluate transplant program performance. The Committee established a framework while developing this proposal that will be used to continue to consider improvements to the performance review process through the evaluation of the effectiveness of this proposal as well as the consideration of other measures that may become available in the future to continue to drive better transplant program performance.

Background

Criteria for review of transplant program performance has been included in the bylaws since as early as 1987.[3] Since that time, programs have been evaluated based on their one-year patient and graft survival rates. The initial criteria identified any transplant program whose survival rates fell into the bottom five percent of transplant programs. Over time, the criteria have been adjusted to incorporate advances in statistical analysis. For example, in 1992, criteria were updated to incorporate risk-adjustment, meaning individual donor and recipient characteristics are considered when calculating a program's expected survival rate[4] and further refined in 2003.[5,6] In 2014, criteria were updated to incorporate the Bayesian methodology.[7] The Bayesian methodology and changes to the thresholds improved the ability of the MPSC to identify potentially underperforming medium and small volume programs. However, other

[1] https://optn.transplant.hrsa.gov/members/committees/membership-and-professional-standards-committee/
[2] https://optn.transplant.hrsa.gov/media/2392/executive_publiccomment_strategicplan_20180122.pdf
[3] United Network for Organ Sharing (UNOS) Bylaws, Appendix B (3) *Survival Rates*, effective August 10, 1987
[4] UNOS Board of Directors minutes. June 24-25, 1992. Available upon request.
[5] Minutes OPTN/UNOS Board of Directors Meeting. June 26-27, 2003. Available upon request.
[6] Briefing Paper Proposed Modification to By-Laws, Appendix B, Section III, C (8) Survival Rates. 2003. Available upon request.
[7] Briefing Paper for Proposal to Review the Current Method for Flagging for Transplant Program Post-transplant Performance Reviews, June 2014. Available upon request.

attempts to modify the transplant program performance requirements stalled. In 2014, the MPSC sponsored a public comment proposal to incorporate a composite pre-transplant metric in the review process, but the MPSC did not submit the proposal to the Board of Directors for approval due to concerns raised during public comment. In 2016, the MPSC sponsored a public comment proposal to shift to a four-tier review method that would continue to exclusively utilize the one-year patient and graft survival metric, but this likewise was not pursued further due to concerns raised during public comment.

One common critique of the current system is its reliance on a single, post-transplant survival metric. Many in the community have questioned whether this singular metric sufficiently assesses the various aspects of program performance. Community members have also suggested that the overemphasis on post-transplant outcomes may result in risk-aversion and decreased transplant volumes.[8]

In 2018, the OPTN President established the OPTN Ad Hoc Systems Performance Committee (SPC), and charged the SPC with considering metrics and elements that could be universally accepted as performance standards, not only for transplant programs, but also for organ procurement organizations (OPOs) and the transplant system as a whole.[9] The SPC also considered ways the OPTN could support system performance. In its report to the OPTN Board of Directors in June 2019, the SPC provided recommendations across four areas, including performance monitoring enhancements.[10] 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.

Proposal for Board Consideration

To develop a proposal that met the key goals of the project, the MPSC evaluated the purpose of MPSC performance monitoring of transplant programs, the elements of the transplant process, what metrics reliably evaluate key aspects of transplant program patient care, and appropriate boundaries for each metric that accurately identify transplant programs that may pose a potential risk to patient health or public safety while reducing the number of false positive identifications.

The MPSC proposal establishes four metrics that measure discrete aspects of care provided by transplant programs:

- Two pre-transplant metrics that measure waiting list management and offer acceptance practices
- Two post-transplant metrics that measure early post-transplant graft survival prior to the recipient being released for longer term care and post-transplant graft survival following release to long term care up to one year.

The MPSC proposes boundaries for each metric that will identify clinically significant outliers. Under the proposal, a transplant program will enter review if it meets the criteria for any of the four metrics

[8] Jay C & Schold J. Measuring transplant center performance: the goals are not controversial but the methods and consequences can be. *Curr Transplant Rep.* 2017; 4(1): 52-58.
[9] https://optn.transplant.hrsa.gov/members/committees/ad-hoc-systems-performance-committee/
[10] Neil H, Overacre B, Rabold M, Haynes CR. Briefing paper ad hoc systems performance committee report. https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf.

contained in the bylaw. Additionally, there are separate criteria for adult and pediatric transplants. The proposal re-organizes and clarifies, but does not substantively change, transplant program obligations to participate in the performance review process. In addition, the proposal includes a new section in Appendix M, *Review and Actions* that codifies the current peer review process. Other administrative changes have been made to Appendix M, *Review and Actions* to ensure consistency with the new peer visit section and Appendix N: *Definitions* to delete definitions for two defunct MPSC standing subcommittees and update the definition for the SRTR. Post-public comment, the MPSC replaced the term "waitlist mortality" with "pre-transplant mortality" which is consistent with a recent SRTR change and added brief descriptions of each of the four metrics to Appendix N: *Definitions*. Finally, the MPSC will also operationally establish an optional performance improvement or "yellow" zone. A transplant program that falls within the yellow zone will be notified and offered assistance, if desired. Transplant programs in the yellow zone will not be obligated to interact with the OPTN.

Measures Selected

Initially, the MPSC determined the elements of the transplant process that are impacted by transplant programs and which elements should be measured by the MPSC for performance monitoring. The MPSC discussed the continuum of care transplant programs provide to patients and identified potential measures to assess a program's performance in each area, which combined can provide a more holistic review of transplant program performance. The MPSC sought to identify metrics that measured independent and distinct phases of transplant care, rather than relying on a single one-year post-transplant survival metric. The MPSC wanted to avoid utilizing overlapping metrics, which the MPSC felt may result in an inappropriate increase in programs being identified for review. The MPSC also reviewed data on the correlation between various metrics to ensure that the Committee selected at least one metric for each phase of care, and that the metric chosen independently measures a program's performance on that phase.

The MPSC ultimately identified two main areas along the continuum of care: waitlist management (pre-transplant care) and post-transplant outcomes. Within those areas, the MPSC further identified specific phases to evaluate. For waitlist management, the MPSC identified waiting list patient care and organ offer acceptance practices. For the post-transplant outcomes aspect of patient care, the MPSC identified peri-operative care and post-operative patient care. In its collective experience, the committee believes that patient outcomes pre-transplant are as important as post-transplant outcomes in the assessment of transplant program performance and quality as research has shown that post-transplant outcomes are better than outcomes for patients that remain on the waiting list.[11]

Within the context of the above framework, the MPSC considered measures the SPC recommended for consideration, additional elements that were identified by the SPC as important but were not prioritized as highly as the recommended elements, and measures suggested by MPSC members. (See SPC Report to the OPTN Board of Directors[12]). The MPSC evaluated each of these measures and chose metrics for inclusion only if the metric met each of the following requirements:

- Measures aspects of care that are clearly within the authority of the OPTN

[11] Schold JD, Buccini LD, Goldfarb DA, Flechner SM, Poggio ED, Sehgal AR. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. *Clin J Am Soc Nephrol*. 2014;9(10):1773-1780. doi:10.2215/CJN.02380314

[12] Neil H, Overacre B, Rabold M, Haynes CR. *Briefing paper ad hoc systems performance committee report*. https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

- Measures aspects of care that the transplant program can impact
- Has a clear desired outcome
- Does not require collection of new data or development of a new metric
- Measures a discrete aspect of transplant care provided by transplant programs
- Is risk-adjusted
- Incentivizes behaviors that will increase transplantation

Alternatives Considered

The MPSC evaluated measures suggested by the SPC, as well as additional measures suggested by MPSC members, using the requirements described above. Many of the suggested measures were eliminated from consideration based on a failure to meet one or more of the established requirements. The sections below explain the requirements used by the MPSC and address the MPSC's basis for removing a number of the suggested measures from consideration.

Lack of OPTN Authority

The MPSC eliminated any potential metric that included evaluation of pre-listing performance, such as percent of patients referred for evaluation that a program adds to the waitlist, the amount of time between the referral and the program's listing decision, and an intent-to-treat analysis. A number of comments, noting that the addition to the waiting list is an area of significant importance to patients, supported the use of a pre-listing measure, such as evaluation rate as a percentage of all referrals, time to listing from referral, and proportion of patients listed within a predefined time interval. Some comments also noted that such measures would also align with Center for Medicare and Medicaid (CMS) requirements for dialysis centers and nephrologists under the ESRD Treatment Choices (ETC) Model and the ESRD Quality Incentive Program (QIP) that includes the Percentage of Prevalent Patients Waitlisted (PPPW) measure. During the development of the proposal, MPSC members agreed that pre-listing measures are important aspects of a program's performance that have a significant effect on patients. However, the MPSC acknowledged that the OPTN is not currently charged, by regulation or contract, to collect data regarding the pre-listing phase, and lacks other means to evaluate these areas. As a result, the MPSC removed those measures from consideration for this proposal. If it is determined that collection of this data or the evaluation of this phase of care is within the authority of the OPTN, the MPSC may consider the use of a pre-listing metric to evaluate transplant program performance in the future, after sufficient data are collected.

Metrics Transplant Program Cannot Sufficiently Impact

The MPSC considered, but ultimately, rejected transplant rate, overall survival from listing, and time to transplant metrics. These metrics either describe system performance rather than transplant program performance, or incorporate data from multiple phases of transplant program patient care or phases of transplant care under the control of other organizations. The MPSC recognized that these metrics demonstrate how well the overall system is functioning and agrees that system metrics should be evaluated. However, because the MPSC is charged with evaluation of individual transplant program performance, the MPSC's performance monitoring review process must focus on discrete metrics that transplant programs are able to sufficiently influence.

No Clearly Defined Data or Outcome

The MPSC eliminated from consideration any metric that did not have a clearly defined desired outcome, such as active versus inactive waitlist status, length of stay, and offer response time. During public comment, the National Kidney Foundation supported an evaluation of patients active status on a program's waiting list rather than use of the waitlist mortality rate, noting that "patients . . . report that remaining active on the list, knowing activation status, and time on the waitlist are more relevant than waitlist survival and would be more patient-centered measures of the patient's experience of the process. Alternative metrics to assess and improve waitlist management (such as % of patients active on the waiting list, or % of total time on the waiting list spent in active status) could be considered instead."

In considering these types of measures, the MPSC noted that whether a candidate should be active or inactive and whether a program should have fewer or greater number of inactive candidates is unclear. For example, a transplant program's active management of or failure to manage its waiting list could both result in a large number of inactive candidates on the program's waiting list. In addition, the MPSC felt utilizing this metric might incentivize undesirable program behavior, such as maintaining a candidate as active when the candidate is not currently appropriate for transplant. The MPSC was concerned that such behavior could ultimately result in potential organ underutilization, if organ offers were increasingly made to candidates who were not in fact ready for transplant and the allocation system was therefore made to be less efficient. The MPSC also did not consider metrics where the data was not clearly defined, such as offer response time.

Developing New Metrics

The MPSC determined it was important for any new performance monitoring system to utilize measures that are currently available. The MPSC discussed three patient care aspects that fall within this category: a waiting list management process measure, a longer-term post-transplant outcome measure, and a post-transplant quality of life measure but determined that the time it would take to develop new measures and collect applicable data would significantly delay any progress on this project, and the MPSC felt it was imperative that action be taken quickly to improve the current system. At the same time, the MPSC acknowledges the potential benefit that new measures can have on this process. As new measures become available in the future, the MPSC is committed to considering whether those measures should be incorporated into the performance monitoring system, or should replace any of the existing measures.

The MPSC recognizes the benefit of evaluating transplant recipient long-term outcomes, noting that a five year measure could incentivize programs to improve efforts to maintain a relationship with recipients in providing follow-up care, and improve the transition of recipients to community care. However, the only currently available longer-term post-transplant outcome metric is the SRTR's three-year graft and patient survival metric.[13] Because the three-year survival rates are calculated using data from transplants performed four to six years earlier, the MPSC did not feel the data was timely enough to be utilized in performance monitoring. In other words, by the time a transplant program would be identified for performance review using those data, the problem either would have already have been going on for too long, or the problem may have resolved itself if the MPSC looked at more recent data.

[13] Scientific Registry of Transplant Recipients. Technical Methods for the Program Specific Reports. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/. Accessed June 28, 2021.

However, the SRTR is actively developing a five-year period prevalent metric.[14,15] Period prevalent cohorts focus on more recent program performance while evaluating longer-term outcomes. The MPSC is supportive of this metric in concept, and requested feedback in public comment about future use of this metric. A number of comments were received in response to this question, the majority of which supported the use of a longer term post-transplant survival metric. A few comments were opposed to use of a longer-term metric noting support for having good outcomes long term but emphasizing that programs do not typically provide primary care past 6 months or 1 year and requiring programs to take control of recipient care beyond one year is unfair to the program. Other comments noted that a longer term survival metric is important to patients since patients expect a graft to survive long past one year. One clinician noted that increased patient value comes from 3 year survival metrics, and longer. For example, in the context of kidney, survival for one-year with a low GFR is not a good outcome since the patient will probably need re-transplant within a year or two due to graft failure. Additionally, the OPTN Pediatric Transplantation Committee and other pediatric transplant professionals strongly encourage the incorporation of longer term outcomes in the future as current time periods are very short compared to expected decades of survival for most pediatric recipients. Some of the supportive comments preferred a three-year rather than a five-year survival metric. The MPSC will monitor the development and evaluation of a longer term period prevalent metric by the SRTR and consider whether it can be incorporated into the performance monitoring system.

Risk Adjustment

The MPSC endorsed the use of risk adjustment for any metrics used in the evaluation of transplant program performance concluding that risk-adjusted measures incentivize programs to list and transplant sicker patients and utilize organs from higher risk donors. When a program lists or transplants a patient with known risk factors, the number of *expected* events for that program increases by a greater amount than it would for a less-risky patient; as long as *observed* outcomes are equal, programs that list or transplant higher-risk patients can achieve a lowered observed-to-expected ratio.

Some comments reiterated a known complaint against risk adjustment: that it results in a competitive comparison of programs. In developing the proposal, the MPSC discussed that some in the transplant community have suggested risk-adjustment inappropriately compares programs to each other. In fact, risk-adjustment does not compare one program against another program, it compares a program against what would be expected to happen if that program performed like other programs around the country collectively for similar candidates, offers for similar organs, and similar transplants. For example, the post-transplant survival model would only expect certain high-risk recipients to survive if similar high-risk patients were surviving at other transplant programs around the country. The best data available to evaluate how the acuity of recipients or the quality of donor organs affect the probability of graft loss is the collective experience of transplant programs across the country with recipients and donor organs with similar characteristics. In its collective expertise, the MPSC felt that lack of risk-adjustment would in fact make transplant programs more risk-averse and could result in the unintended negative consequence of greater organ discard. Therefore, the MPSC eliminated from consideration any metric that did not include some level of risk-adjustment.

[14] Scientific Registry of Transplant Recipients. SRTR Review Committee Meeting Minutes. April 27, 2021. https://www.srtr.org/media/1486/srtr-review-committee-meeting-minutes-20210427.pdf. Accessed June 28, 2021.
[15] Wey A, Hart A, Salkowski N, Skeans M, Kasiske BL, Israni AK, et al. Posttransplant outcome assessments at listing: Long-term outcomes are more important than short-term outcomes. *AJT*. 2020: 20(10): 2813-2821. doi: 10.1111/ajt.15911

Although use of risk adjusted metrics was widely supported in public comment, the American Society of Transplant Surgeons (ASTS), in its public comment and in a white paper published earlier this year[16], rejected risk adjustment. The ASTS noted that risk adjustment results in a moving "expected" target, which makes it difficult for transplant programs to predict if they will be identified for review. The ASTS also noted issues with the current risk adjusted models for post-transplant survival. Specifically, the models have a very wide spectrum of disease morbidity that some programs code more liberally than others, and the models do not include some variables known to impact survival. Based on these concerns, the ASTS does not believe that risk adjustment is trusted by transplant hospitals. Instead, the ASTS suggests using an unadjusted fixed floor percentage survival to identify programs for review. The fixed floor threshold would be based on expected patient survival with alternative therapy when available with adjustment to justify the risk and cost of transplantation and to protect patient safety. For example, a kidney program would only be identified for review if its observed (raw) post-transplant one-year patient and graft survival fell below 90 percent, or another fixed number. The ASTS suggested that a potential secondary analysis could be implemented, which would use a simplified risk adjustment to further evaluate whether programs that did not meet the fixed floor boundary should be subject to MPSC review.

The MPSC discussed whether to utilize a fixed-floor approach when setting the boundaries for each metric and acknowledges that a fixed floor percentage survival is easier to understand. However, as described previously, the MPSC felt that risk-adjustment is an important aspect of incentivizing listing and transplantation of higher-risk recipients and utilizing organs from higher-risk donors. If the MPSC and the transplant community acknowledge that transplant programs have different risk profiles – different patient acuity, different case mix, and different donor availability depending on where they are located and the donor supply - the way to reflect that is through risk adjustment. Risk adjustment is a widely vetted and widely accepted methodology for comparing healthcare outcomes.

Specifically, using a fixed floor with unadjusted measures would mean that programs would not see any statistical benefit from transplanting sicker patients or using organs from higher risk donors; all programs would be expected to achieve the same observed survival rate, regardless of the acuity of their patients or the quality of the donor organs they transplant. In other words, there would be no room for error, particularly in any low-risk transplants. The easiest way for a transplant program to achieve a fixed floor would be to limit risk taking by not listing higher risk candidates or accepting higher risk donor organs. The only way to avoid risk averse behavior would be to set the fixed floor so low that a program would not be identified for appropriately transplanting a significant number of higher risk recipients and using a significant number of higher risk organs. However, setting the floor very low could result in the failure to identify a program that is performing a larger number of lower risk transplants with a concerning number of events in lower risk transplants that poses a risk to patient health and public safety.

The MPSC does not agree with the suggestion that a fixed floor set slightly higher than survival on alternative therapies would adequately identify transplant programs that pose a risk to patient health or public safety. The example is often given in the context of kidney transplant and dialysis and does not address the fact that for other organs, the survival rate on alternative therapies is arguably 0% since there are limited, if any, viable long term alternative therapies. Moreover, a survival rate slightly higher

[16] American Society of Transplant Surgeons. White Paper on Optimization of Transplant Center Assessment. January 12, 2021. https://asts.org/docs/default-source/regulatory/asts-white-paper-on-optimization-of-transplant-center-assessment-january-12-2021.pdf?sfvrsn=43a46d3_2. Accessed June 29, 2021.

than dialysis, or potentially lower once a secondary analysis is performed using risk adjustment, is not necessarily an acceptable outcome for patients; not only is the recipient harmed by failure of an organ but another patient waiting for transplant is also harmed by not receiving a transplant.

The use of a fixed unadjusted floor raises additional issues to consider. If risk adjustment is not used to address the acuity of patients and quality of donor organs, programs in certain geographical areas that have a higher percentage of the population with patient and donor risk factors would likely be disadvantaged under the system. This could lead to calls for regional variances in the fixed floor resulting in a more complex system rather than a simpler system. The best way to account for these geographical differences is to adjust for these risks when identifying programs for review.

The final concern raised by ASTS and others with the use of risk adjustment is that not all variables known to impact survival are included in the SRTR models. As noted in the public comment document, the MPSC discussed anecdotal concerns within the transplant community about the comprehensiveness of the current risk-adjustment models during the development of the proposal. The MPSC does not believe that the lack of perfect risk adjustment supports the rejection of risk adjustment all together. During the MPSC discussions, the SRTR described its process for developing the risk adjustment models, noting that they routinely evaluate all data collected by the OPTN for correlation with risk and incorporate the data into the models that captures risk without overfitting the model. In other words, in making the decision to include a data point in a model, the SRTR determines whether a particular data point enhances the predictive ability of the model and whether that data point captures a risk not already captured through other data included in the model. The SRTR also has a process for receiving requests from the community to review additional data points to determine if a new variable should be added to the model. The MPSC fully supports working with the SRTR and the transplant community to identify clinical variables that can improve risk adjustment models, resulting in either an evaluation of data already collected or a referral to the OPTN Data Advisory Committee for collection of additional data.

The MPSC reviewed and discussed the results of public comment on the topic of risk adjustment and concluded the public sentiment supports sending the proposal to the Board with no changes on this topic. The MPSC has an oversight obligation under the Final Rule and the OPTN contract to monitor the performance of transplant programs and to identify and address improvement opportunities at transplant programs that may pose a risk to patient health and public safety. The MPSC, as a peer group, also serves as a partner and resource to assist transplant programs to increase transplants while providing excellent patient care. Abandoning risk adjustment and setting an unreasonably low fixed floor threshold for identification of transplant programs for MPSC performance review would jeopardize the MPSC's ability to perform these essential roles.

Pre-Transplant Waitlist Management

Of the pre-transplant measures recommended by the SPC, only the waitlist mortality rate (or pre-transplant mortality rate)[17] and offer acceptance rate met the MPSC's required criteria. The MPSC assessed whether these measures sufficiently represent two distinct aspects of pre-transplant care.

[17] As of July 6, 2021, waitlist mortality rate is now referred to as the pre-transplant mortality rate on the SRTR website (https://www.srtr.org/) and in the transplant program specific reports (PSRs) (https://www.srtr.org/reports/program-specific-reports/). Prior to submission to the Board for approval, references to the names of metrics will be reviewed for consistency with the terminology used in reports by the SRTR.

First, the Committee evaluated data provided by the SRTR, which showed a minimal correlation between the program outcomes on these two metrics.[18] Additionally, after the MPSC established boundaries, the Committee reviewed data on programs that would be identified. The data showed that of 27 programs that met the proposed criteria for these two metrics, no programs were identified by both.[19]

The MPSC discussed the benefits and the disadvantages of use of the waitlist mortality rate to assess a program's waitlisted candidate care. The waitlist mortality rate is risk-adjusted and has already been available to transplant programs for a significant time. It measures an aspect of transplant care post-listing, namely whether candidates listed at a transplant program gain the benefit of transplant by staying alive following listing and before any subsequent transplant.[20] On the one hand, the MPSC acknowledges often-communicated criticism that this metric is not useful for kidney transplant programs since they typically do not provide direct care to patients on the waiting list. Therefore, the health and mortality of patients on a kidney waiting list may be outside the control of the program. The proposal received a significant number of comments that raised this very concern, including from organizations representing kidney professionals, dialysis providers and patients; and from member transplant hospitals and transplant professionals. Some also expressed concern that programs will respond by limiting access of higher-risk, sicker patients to the waiting list based on a fear, even though unwarranted, that listing sicker patients and the potential increase in pre-transplant deaths could result in being identified for review. Other comments noted that if use of this measure results in programs restricting access to the waiting list, it would conflict with CMS measures applied to dialysis facilities and nephrologists to increase access generally and decrease disparities in access to kidney transplant. The MPSC discussed this issue extensively. Although many kidney transplant programs may not medically manage the candidates on their waiting list, the MPSC asserts that a program, by listing a patient, takes on a certain level of responsibility to do what it can to increase the likelihood that a patient makes it to transplant alive. In order for efforts to improve efficiency in the system, decrease cold ischemic times, decrease organ discards and increase access to transplant to be successful, kidney transplant programs must play a role in creating a healthy waiting list that will increase the likelihood that patients gain access to transplants, not just to a transplant program's waiting list.

As discussed generally in the risk adjustment section and more specifically in relation to waitlist mortality in the paragraph below, the risk adjustment contained in the model is intended to eliminate, or at least significantly reduce, the effect of differences in the acuity of patients from the measurement of waitlist mortality. The data demonstrates that, once risk adjusted, there is not significant variability in the waitlist mortality rate among kidney transplant programs, as demonstrated by the fact that zero kidney programs were identified when the waitlist mortality criteria was applied to the Spring 2020 PSR dataset. However, because there is less variability in the waitlist outcomes of kidney patients, if a kidney program did meet the criteria, and as such, was an outlier in waitlist mortality, the program has the responsibility to evaluate why the waitlist mortality is so high and take action to improve, potentially through consultation with a primary provider or dialysis unit to provide education or guidance. Although the lack of variability in the waitlist mortality rate among kidney transplant programs decreases the impact of this metric for kidney transplant programs as opposed to other organ transplant programs,

[18] Scientific Registry of Transplant Recipients. MPSC workgroup: Investigating the relationships of different metrics. https://tools.srtr.org/mpsc_shiny_dashboard/. Accessed June 28, 2021.
[19] Data presented by UNOS staff to MPSC Performance Monitoring Enhancement Subcommittee on May 7, 2021. Available upon request.
[20] Scientific Registry of Transplant Recipients. Technical Methods for the Program Specific Reports. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/. Accessed June 28, 2021.

the MPSC asserts that it is important to align the metrics for all organs to identify overall outliers rather than a separate set of metrics for each organ type.

Concern that transplant programs may respond to the use of waitlist mortality by limiting the listing of sicker patients, thereby reducing access to the waiting list and reinforcing existing disparities in access to transplantation, was not limited to kidney transplant. During the development of the proposal, the MPSC discussed at length common misperceptions about the metric and the risk adjustment in the model, such as the assertion that the waitlist mortality rate can be manipulated by simply adding many relatively healthy, low-risk patients to the waiting list, or the idea that adding sicker patients to the waiting list would adversely affect a program's waitlist mortality rate. Some Committee members were concerned that these misperceptions would nevertheless deter programs from listing sicker patients, resulting in an unintended consequence of decreasing access to transplant. The Committee acknowledged that the risk adjustment accounts for these risks appropriately and a program would not benefit by engaging in risk averse behaviors that are not in the interests of patients. For example, the model would expect relatively healthy, low-risk patients to survive for a longer time on the waiting list and would expect sicker patients to not survive as long. A program's metric would only be adversely affected if the relatively healthy, lower-risk patients did not survive once listed. A program's metric would be positively impacted if a sicker patient survived longer than expected once listed. These misperceptions were echoed in comments received on the proposal and indicate a need for additional education on the risk adjustment in the waitlist mortality model and how the risk adjustment accounts for many of the scenarios that appeared to raise concerns.

Committee members also noted a number of benefits of use of the waitlist mortality rate. It would encourage programs to examine how to improve the care of candidates on the waiting list, potentially through activities like education and outreach to referring physicians. Additionally, utilizing this metric would encourage programs to examine how to actively manage the waiting list, through activities like a periodic re-evaluation of listed candidates for suitability for transplant. The MPSC noted that evaluation of waitlist mortality, in combination with a reduced emphasis on post-transplant outcomes, could also incentivize more aggressive offer acceptance practices as studies have demonstrated that the probability of waitlist mortality increases after at least one declined offer.[21,22,23,24,25,26] The Association of Organ Procurement Organizations (AOPO) echoed this sentiment noting that waitlist mortality is particularly important as the system shifts to a patient-centric understanding of risk-benefit which must evaluate the risk to a candidate of receiving an offered organ versus the risk to a candidate of not receiving the organ offered; further noting that this paradigm is incredibly important to support through aligned performance metrics if the system is intent on better utilizing the available organ pool which is increasingly from older and medically complex donors. Use of the waitlist mortality rate metric could encourage review and improvement of systems issues that are barriers to getting patients transplanted

[21] Husain A, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, et al. Association between declined offers of deceased donor kidney allograft and outcomes in kidney transplant candidates. JAMA Netw Open. 2019 Aug 2;2 (8):e1910312.
[22] Goldberg, DS, French B, Lewis JD, Scott FI, Mamtani R, Gilroy R, et al. Liver transplant center variability in accepting organ offers and its impact on patient survival. *J Hepatol.* 2016; 64(4): 843-851.
[23] Lai JC, Feng S, Roberts JP. An examination of liver offers to candidates on the liver transplant wait-list. *Gastroenterology* 2012; 143(5): 1261-1265.
[24] Choi AY, Mulvihill MS, Lee HJ, Zhao C, Kuchibhatla M, Shroder JN, et al. Transplant center variability in organ offer acceptance and mortality among US patients on the heart transplant waitlist. *JAMA Cardiol.*, 2020; 5(6): 660-668.
[25] Mulvihill MS, Lee HJ, Weber J, Choi AY, Cox ML, Yerokun BA, et al. Variability in donor organ offer acceptance and lung transplantation survival. *J Heart Lung Transplant*, 2020: 39(4): 353 – 362.
[26] Cox ML, Mulvihill MS, Choi AY, Bishawi M, Osho AA, Haney JC, et al. Implications of declining donor offers with increased risk of disease transmission on waiting list survival in lung transplantation. *J Heart Lung Transplant*, 2019; 38(3): 295-305.

before they die without receiving a transplant. Others noted that use of the metric could also discourage listing of patients who are unlikely to benefit from transplant. Finally, Committee members noted that as the community moves to continuous distribution systems where acuity of patients is a significant factor, some of the previous concerns that use of this metric would deter programs from listing sicker patients may no longer be as relevant. If programs avoid adding sicker patients to the waiting list, the program is less likely to get offers and perform transplants. The MPSC ultimately determined that the waitlist mortality rate is the most effective currently available metric to measure waiting list candidate care. As described above, the MPSC reviewed and discussed the results of public comment regarding use of the waitlist mortality rate for evaluation of transplant programs and concluded the public sentiment supports sending the proposal to the Board with no changes on this topic.

Regarding offer acceptance practices, the MPSC noted that the offer acceptance rate metric has been available to programs via the SRTR for a number of years and is risk adjusted, and transplant programs have significant, if not total, control over this metric. Also, use of offer acceptance rate is consistent with initiatives under Goal 1: Increase the number of transplants in the 2021-2024 OPTN Strategic Plan.[27] Public comments were generally supportive of the use of offer acceptance to monitor transplant program performance. A patient organization noted this metric is fundamental to improving the current system and will reduce discards, encourage programs to have regular conversations with patients about organ preferences, and encourage appropriate use of OPTN screening criteria and filters. Comments from the OPO community support this metric as a good tool to streamline organ placement which would increase system efficiency and align with the goal for both OPOs and transplant programs of increasing organ utilization. Comments noted that more realistic use of the screening criteria and offer filters by transplant programs will improve the ability of OPOs to identify accepting programs more efficiently and timely. However, some comments expressed concern that use of offer acceptance will discourage the use of broad donor criteria reducing the ability of programs to evaluate each organ to maximize patient opportunity for transplant. Several comments from members of the pediatric transplant community noted that pediatric components generally use broad donor criteria and have higher number of declines because more stringent guidelines for organ quality are used and often organs that appear appropriate initially are determined to be inappropriate based on anatomy. Some comments expressed concerns that offer acceptance could result in increased selection bias among programs as there may be high acceptance rates for conservative programs and a decrease in acceptance rate for programs that accept more marginal offers. The ASTS suggested that reducing disincentives to transplantation may increase transplantation in a manner that modifies both organ offer acceptance and waitlist mortality practices, such that metrics evaluating both pre-transplant phases of care may be unnecessary. The MPSC reviewed and discussed the results of public comment regarding use of the offer acceptance for evaluation of transplant programs and concluded the public sentiment supports sending the proposal to the Board with no changes on this topic for the reasons below.

Initially, the MPSC notes that the offer acceptance model is the most complex of the models built by the SRTR due to the large amount of available data. Therefore, the model adjusts for an extensive number of donor factors and recipient factors, sequence number of the candidate for which the offer is received, and candidate's distance from the donor hospital.[28] However, as with the waitlist mortality rate metric, the MPSC discussed at length common misperceptions about the offer acceptance rate metric in the community. One of the biggest misunderstandings seems to be around which offers are included in the

[27] OPTN Strategic Plan. https://optn.transplant.hrsa.gov/governance/strategic-plan/
[28] Scientific Registry of Transplant Recipients. SRTR risk adjustment model documentation: offer acceptance models. https://www.srtr.org/tools/offer-acceptance/. Accessed June 28, 2021.

metric; the MPSC feels it is important to note that programs are only evaluated on offers they receive and decline and that another program accepts and transplants. Offers are not included if the organ offered is not eventually transplanted. If a program never receives an offer due to the use of screening criteria and offer filters that screen their candidates off the match run, the program's organ offer acceptance rate is not impacted.

Additionally, the MPSC noted that the percentage of offers accepted nationally is quite low, as shown in **Table 1** below.

Table 1: National Average for Offer Acceptance by Organ in SRTR Fall 2020 and Spring 2020 PSR Cohorts.[29]

SRTR PSR Cohort	Heart	Kidney	Liver	Lung	Pancreas
Fall 2020	6.5%	0.76%	3.7%	4.9%	5.4%
Spring 2020	7.0%	0.8%	4.3%	4.9%	6.9%

The MPSC believes evaluating a transplant program's offer acceptance rate will encourage behaviors that can increase the average offer acceptance rate, improve system efficiency and ultimately result in an increase in the number of transplants. First, it will encourage transplant programs to honestly evaluate what organs they are willing to accept for a candidate and use the screening criteria and offer filters in the Waitlist application to eliminate organ offers that the program would never accept. This should decrease the number of offers that must be made in order to place an organ. Screening offers that a program will not accept can improve a poor offer acceptance evaluation, which is an intended consequence of use of this metric. The MPSC reiterates that the intent is not to encourage programs to use screening criteria to eliminate more marginal organ offers that the program might accept. The extensive SRTR offer acceptance model incorporates numerous risk factors designed to account for candidate and donor factors and the interaction between candidate and donor characteristics such as height, age or body surface area ratios and distance between recovering and transplant hospital that result in an expectation that offers for more marginal organs that might not be right for that patient, or offers from a long distance that could result in unacceptable cold time are unlikely to be accepted.

Evaluating offer acceptance will also encourage programs to actively manage their waiting lists in order to make sure that candidates who are listed as active are ready for transplant and that candidates who are not ready for transplant are placed in an inactive status. Encouraging the use of offer filters and screening criteria and active waiting list management will contribute to system efficiency in getting organs to the right patient more quickly, thereby streamlining the allocation process and decreasing ischemic time and organ underutilization. The use of offer acceptance rate in combination with a reduced emphasis on post-transplant outcomes will encourage transplant programs to accept more organs, increasing the number of transplants to benefit more patients. Lastly, evaluating programs' offer acceptance rates may even improve waitlist mortality. As noted above, studies have found that the

[29] Scientific Registry of Transplant Recipients. Program-Specific Reports. https://www.srtr.org/reports/program-specific-reports/. Accessed June 28, 2021.

probability of mortality on the waitlist increases when offers are declined.[30,31,32,33,34,35] Being evaluated on offer acceptance will discourage programs from declining offers for transplantable organs, thereby decreasing candidates' risk of mortality on the waiting list.

Post-Transplant Outcomes

The MPSC identified two distinct phases of care for post-transplant recipient outcomes, perioperative care and postoperative care. Perioperative care is an initial period of more intensive patient care post-transplant. For purposes of MPSC measures, perioperative care incorporates list management, recipient selection, surgical care and the effectiveness of the multi-disciplinary team and care pathways prior to release for longer-term maintenance care. Postoperative care follows the release of a recipient to longer-term care and focuses on the transplant program's ability to coordinate and provide recipient care for the long-term post-transplant. Based on the evaluation described below, the MPSC chose 90-day graft survival for the measure to evaluate a program's perioperative phase and 1-year post-transplant graft survival conditional on 90-day graft survival for the measure to evaluate a program's longer term postoperative phase. Both of these metrics would utilize the current 1-year post-transplant survival model cohort of two and a half years. Although there is more correlation between these two metrics than between the two metrics chosen for pre-transplant evaluation, the MPSC's assertion that each of these metrics evaluates a distinct aspect of patient care is supported by the fact that out of 33 distinct programs identified by the proposed boundaries for these two metrics, only two programs were identified by both.[36] Generally, comment supported the use of these two measures of post-transplant outcomes, often with the suggestion of future consideration of a longer term post-transplant survival metric. A couple of comments expressed concern over the addition of a 90-day post-transplant survival metric stating generally that a 90-day post-transplant metric is not meaningful. The MPSC reviewed and discussed the results of public comment regarding use of 90-day graft survival and 1-year conditional on 90 day graft survival for evaluation of transplant programs and concluded the public sentiment supports sending the proposal to the Board with no changes to this topic.

During its evaluation of the appropriate post-transplant measures, the MPSC focused on the currently available one-month, one-year and three-year post-transplant outcomes metrics. As discussed previously, the MPSC did not consider the three-year post-transplant outcomes metric because, as the metric is currently constructed, it includes transplants up to six years prior to the report date, a long period inappropriate for purposes of monitoring recent transplant program performance. The MPSC focused on developing the short-term perioperative care and longer-term postoperative metrics within the one-year post-transplant time frame. When considering the one-month and one-year metrics, the SRTR informed the MPSC that the SRTR could provide reports using an alternative time frame to assess

[30] Husain A, King KL, Pastan S, Patzer RE, Cohen DJ, Radhakrishnan J, et al. Association between declined offers of deceased donor kidney allograft and outcomes in kidney transplant candidates. JAMA Netw Open. 2019 Aug 2;2 (8):e1910312.
[31] Goldberg, DS, French B, Lewis JD, Scott FI, Mamtani R, Gilroy R, et al. Liver transplant center variability in accepting organ offers and its impact on patient survival. *J Hepatol.* 2016; 64(4): 843-851.
[32] Lai JC, Feng S, Roberts JP. An examination of liver offers to candidates on the liver transplant wait-list. *Gastroenterology* 2012; 143(5): 1261-1265.
[33] Choi AY, Mulvihill MS, Lee HJ, Zhao C, Kuchibhatla M, Shroder JN, et al. Transplant center variability in organ offer acceptance and mortality among US patients on the heart transplant waitlist. *JAMA Cardiol.*, 2020; 5(6): 660-668.
[34] Mulvihill MS, Lee HJ, Weber J, Choi AY, Cox ML, Yerokun BA, et al. Variability in donor organ offer acceptance and lung transplantation survival. *J Heart Lung Transplant*, 2020: 39(4): 353 – 362.
[35] Cox ML, Mulvihill MS, Choi AY, Bishawi M, Osho AA, Haney JC, et al. Implications of declining donor offers with increased risk of disease transmission on waiting list survival in lung transplantation. *J Heart Lung Transplant*, 2019; 38(3): 295-305.
[36] Data presented by UNOS staff to MPSC Performance Monitoring Enhancement Subcommittee on May 7, 2021. Available upon request.

short-term post-transplant outcomes. The SRTR also indicated it could produce a 1-year post-transplant outcome metric that is conditioned on whether the graft was functioning at the end of the short-term period.

In order to delineate the appropriate time frame for short-term perioperative care, the MPSC drew on the clinical expertise of its members and SRTR data illustrating the time period in which early graft losses and patient deaths leveled off. Although there are small variations among organs, the data established that early graft loss and patient death events leveled off around the 90-day mark for all organs, as seen in **Figures 1 – 4** below.

Figure 1: Hazard Function for Heart Adult Graft Failure Through 3-Years Post-Transplant

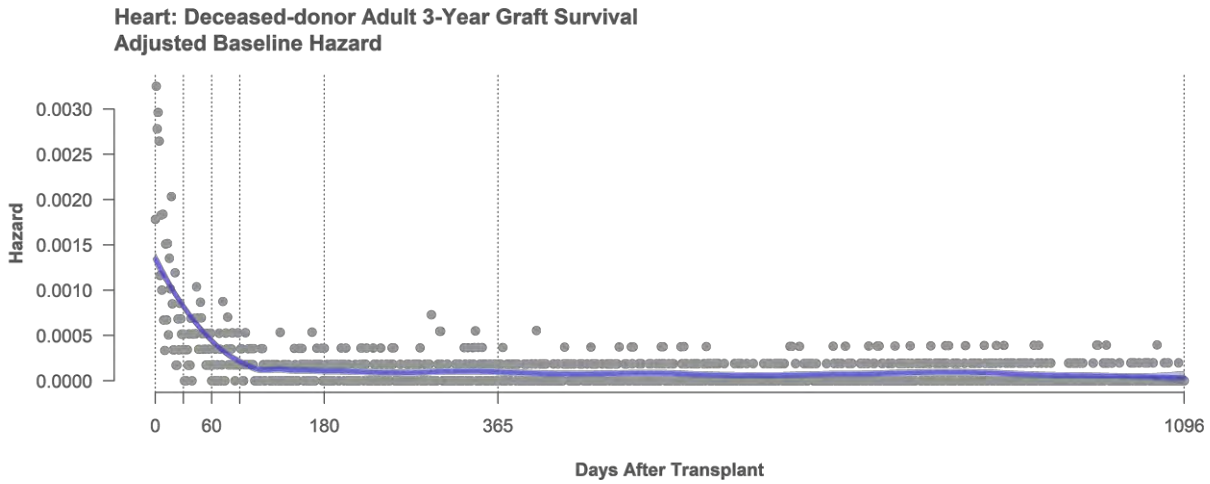


Figure 2: Hazard Function for Kidney Adult Graft Failure Through 3-Years Post-Transplant

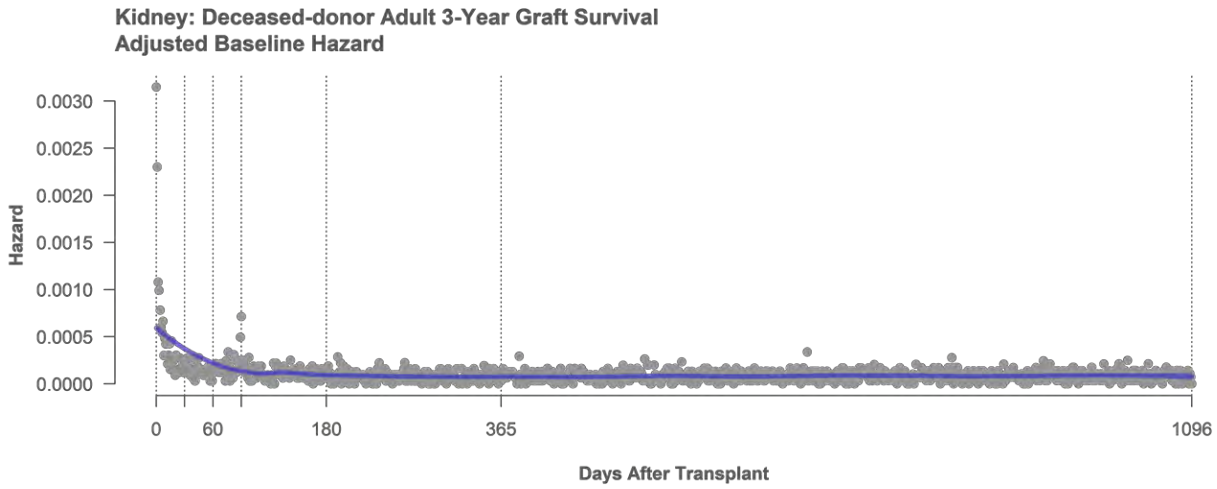


Figure 3: Hazard Function for Liver Adult Graft Failure Through 3-Years Post-Transplant

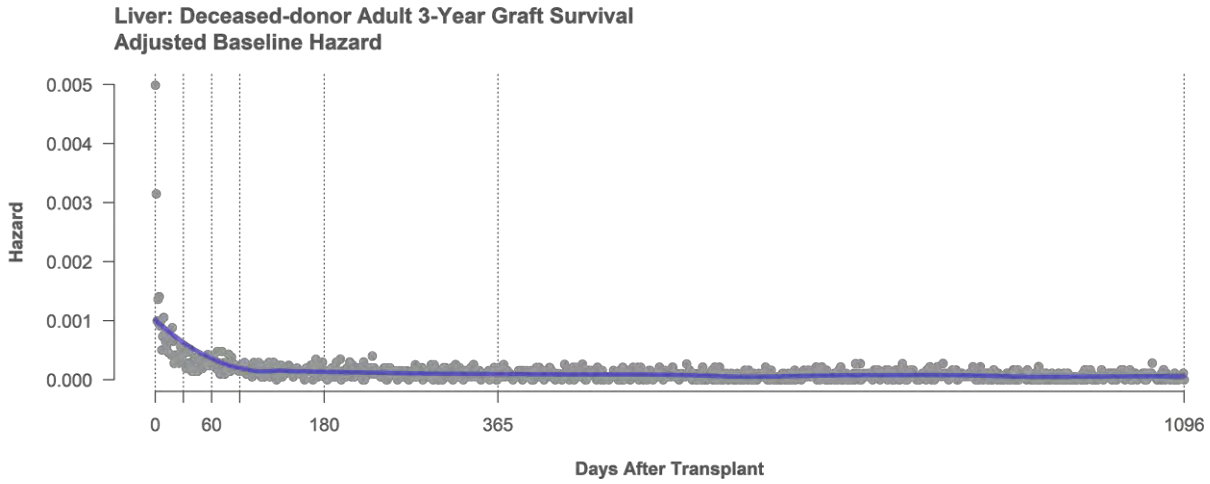
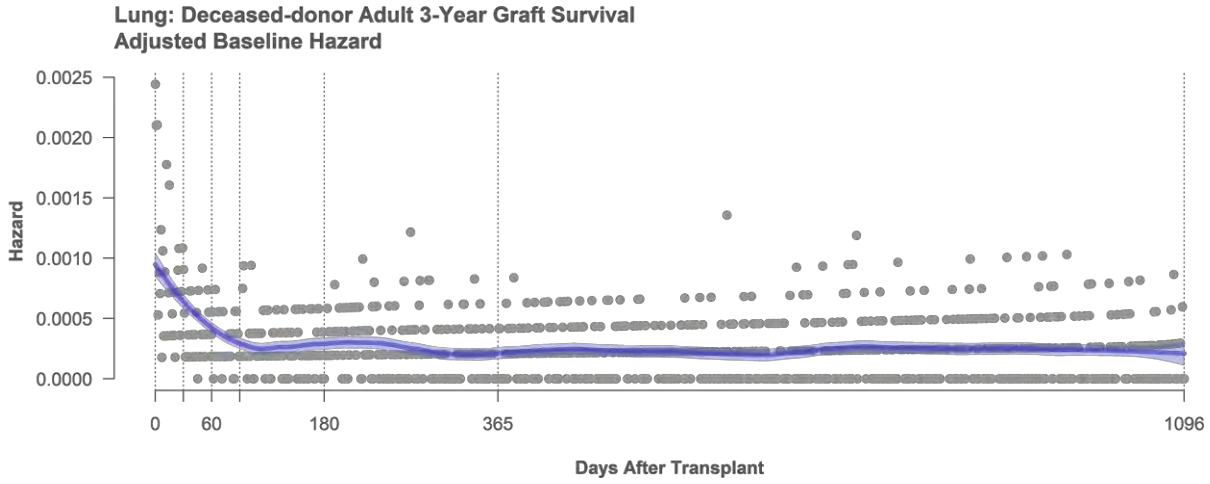


Figure 4: Hazard Function for Lung Adult Graft Failure Through 3-Years Post-Transplant



MPSC members confirmed, based on clinical experience, that this time period roughly coincided with the most intensive recipient care post-transplant for all organs.

In order to ensure that the post-operative metric measures a distinct, independent phase of post-transplant care, the MPSC supports the use of a 1-year longer-term outcome metric that is conditional on graft function at the end of the 90-day period. The conditional 1-year metric cohort would only include those recipients whose graft was functioning at 90-days post-transplant. Using a conditional 1-year metric in conjunction with a 90-day short-term measure will help programs identify and focus on specific areas, either perioperative or postoperative, for improvement of recipient care. As previously stated, the MPSC supports the use of a one-year post-transplant survival conditional on 90-day survival metric initially while committing to evaluating whether to replace this measure with a longer-term post-transplant measure, including but not limited to the development of period prevalent cohorts.

Under the current system, the MPSC evaluates both post-transplant graft and patient survival. The MPSC considered whether it was necessary to continue to evaluate both post-transplant graft and patient survival. Use of either graft or patient survival would simplify the system by limiting the total number of metrics evaluated to four rather than six. A few public comments suggested the use of patient survival rather than graft survival to evaluate post-transplant outcomes suggesting the use of graft survival would disincentivize re-transplants, transplants in highly sensitized candidates and other challenging candidates. The MPSC discussed the importance of patient survival as a reflection of a life saved and acknowledged that saving lives is the ultimate goal of transplantation. The Committee also discussed the necessity sometimes for patients to be re-transplanted in order to survive. However, the MPSC recognized that the graft survival model is the most comprehensive, in that it includes graft losses and patient deaths when determining graft survival and both initial and re-transplants in the cohort are examined.[37] Furthermore, the patient survival model excludes re-transplants and is not well suited for evaluation of kidney transplant programs, where a patient is likely to survive following the loss of a kidney graft. The MPSC felt that failing to capture graft losses, particularly in kidney, would constitute a substantial blind spot for an event with significant patient harm, for both the recipient who lost the graft and for another patient that did not receive a transplant. The MPSC analyzed historical data to assess whether evaluating only graft survival would miss potential patient safety issues that were previously identified through the patient survival metric alone, and identified no such issues. For these reasons, the MPSC determined that if it was going to choose either patient or graft survival rather than monitoring both, the appropriate course would be to evaluate graft survival for post-transplant outcomes since this metric is the most comprehensive and the most likely to identify potential risks to patient health and public safety for both graft loss and patient death post-transplant.

For pancreas transplant programs, the MPSC proposes to continue the current practice of evaluating patient survival only. The SRTR does not currently produce a pancreas graft survival model. A new OPTN policy defining pancreas graft failure was implemented in February 2018[38] so there is not sufficient data following implementation of this new definition to produce a pancreas graft survival model. Once a graft survival model is developed, the MPSC will consider replacing the evaluation of pancreas patient survival with graft survival.

Establishment of Boundaries

Although the OPTN has the authority to perform ongoing, routine evaluation of the performance of every transplant program to identify potential risks to patient health and public safety under the OPTN Final Rule and the OPTN contract, the nature of MPSC performance review necessarily involves a significant commitment of the limited resource of MPSC peers. The OPTN receives data for the relevant metrics for all transplant programs, but has in the past and will continue to use boundaries for each metric that are designed to narrow the transplant programs that actively participate in an intervention with the MPSC to those outlier programs that are most likely to potentially pose a risk to patient health and public safety.

As part of this effort, the MPSC re-evaluated the current process for MPSC review of transplant program performance. In developing a new process, the MPSC emphasizes the importance of self-monitoring,

[37] Scientific Registry of Transplant Recipients. Technical Methods for the Program Specific Reports. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/. Accessed June 28, 2021.
[38] Organ Procurement and Transplant Network. Definition of Pancreas Graft Failure Policy Notice. https://optn.transplant.hrsa.gov/media/1572/policynotice_20150701_pancreas.pdf. Accessed October 22, 2021.

self-examination and self-improvement as part of the performance monitoring process while also serving its oversight responsibility to ensure patient safety. In furtherance of these two goals, the performance review process will include two tiers, the MPSC intervention or "red" zone, and a performance improvement or "yellow" zone. Transplant programs would only be required to interact with the MPSC if the program fell within the criteria for the MPSC intervention (red zone). For the MPSC intervention zone, the MPSC review process will be similar to the current process for review of one-year post-transplant outcomes. Transplant programs identified for performance review receive an initial inquiry regarding program structure, procedures and protocols, quality review processes, and plans for improvement followed by possible additional interactions with the MPSC based on review of that initial submission, such as additional requests for information, informal discussions or peer visits. Programs that fall within the performance improvement zone will not be obligated or expected to interact with the OPTN. The MPSC expects programs in the yellow zone to actively evaluate applicable processes and implement any necessary improvements; whether a program does so on its own or utilizes OPTN resources would not be a factor in a subsequent review if the program moved into the red zone. Therefore, the criteria for this zone are not included in the proposal. The MPSC may change the boundaries for the performance improvement zone over time. Because the performance improvement zone is not an OPTN Obligation, the boundaries for it are not proposed for inclusion in the Bylaws. However, the OPTN will make the performance improvement zone boundaries publicly accessible on its website. The MPSC requested feedback on the performance improvement zone concept. Feedback received during public comment was generally supportive and suggested various strategies for providing assistance to programs that fell within the performance improvement (yellow) zone to help avoid entering the MPSC intervention (red) zone.

For the MPSC intervention zone, the MPSC is proposing independent boundaries for each metric and separate boundaries for adult and pediatric transplants; and proposing that each boundary apply to all organ types including heart, kidney, liver, lung and pancreas. As discussed earlier, the proposed boundary for the two post-transplant outcomes metrics will be applied to patient survival rather than graft survival for pancreas programs. The following sections provide information on the process used to determine appropriate boundaries, the alternatives discussed by the MPSC, and the boundary criteria chosen for the proposal.

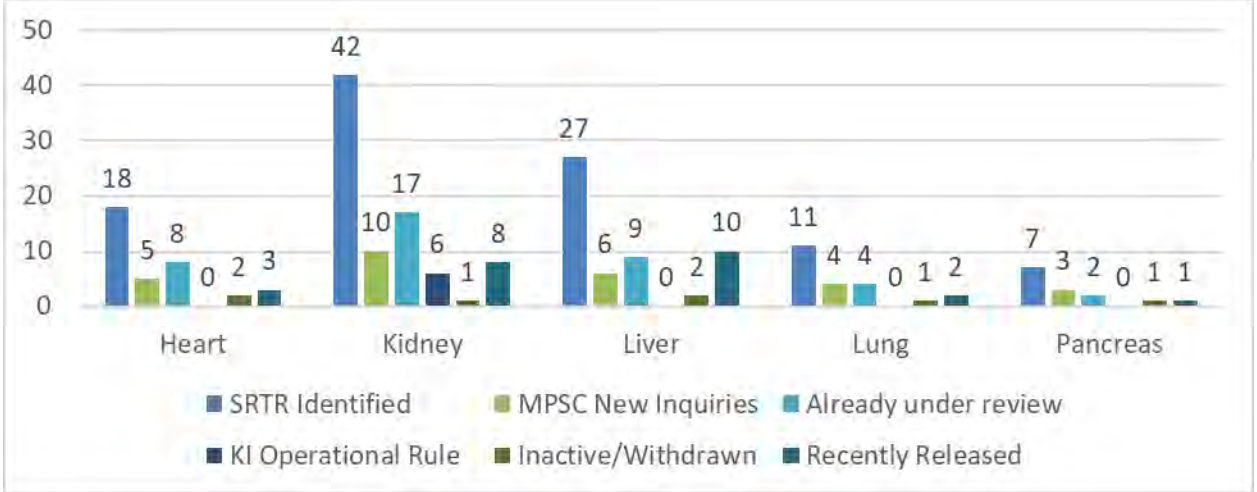
Process for Setting Boundaries

The MPSC decided where to place the boundary for each metric based on a number of considerations. First, the MPSC wanted to focus its review on programs with clinically meaningful differences in performance from their peers. The MPSC felt that programs that are significant outliers would be most likely to need performance improvement assistance in order to avoid a potential risk to patient health or public safety. Second, the MPSC determined, for a number of reasons, that the proposed process should not increase the total number of programs identified for review, even though the number of metrics was increasing. Various comments were received about the process for setting boundaries, including that too many programs are identified, that too few programs are identified, and that the focus should be on identifying all programs that are operating at a sub-optimal level, rather than maintaining a total number of reviews near the current level.

Historically, the MPSC designed the current boundaries to have a 5% false positive rate, in order to have strong confidence that all programs in need of assistance were identified for review.[39] In other words, the current system was intentionally designed in a way that would likely result in some programs being identified for review that are actually performing as expected. The MPSC decided to shift the focus of the new performance system to focus on programs that are outliers and most likely in need of help. This will identify a smaller number of programs in each metric and result in approximately the same cumulative number of reviews. Lastly, and perhaps most importantly, the MPSC acknowledged that increasing the number of programs identified for review might have the unintended consequence of dis-incentivizing transplantation. The MPSC preference to not identify more programs than is identified under the current 1-year post-transplant patient and graft survival criteria was used to provide parameters to the SRTR for modeled data. The MPSC performed additional analysis of the program data prior to finalizing the proposed criteria. This process is described in more detail below.

Please note that the number of "flags" each cycle is not equivalent to the number of unique programs that will enter performance review during that cycle. Under the current system, one program is often identified during multiple reporting cycles and a program could be "flagged" for lower than expected survival on both pediatric and adult transplants, resulting in a much smaller number of new inquiries each cycle. For example, **Figure 5** below notes that out of 105 total "flags" for 1-year post-transplant survival in the Spring 2020 SRTR MPSC reports, only 28 programs (green bars) received an inquiry. Forty programs were already under review (light blue) and 24 had recently been released (teal) after having been "flagged" in previous cycles. [40]

Figure 5: Number of Programs Flagged in Spring 2020 MPSC Reports and MPSC Action Based on Flag by Organ

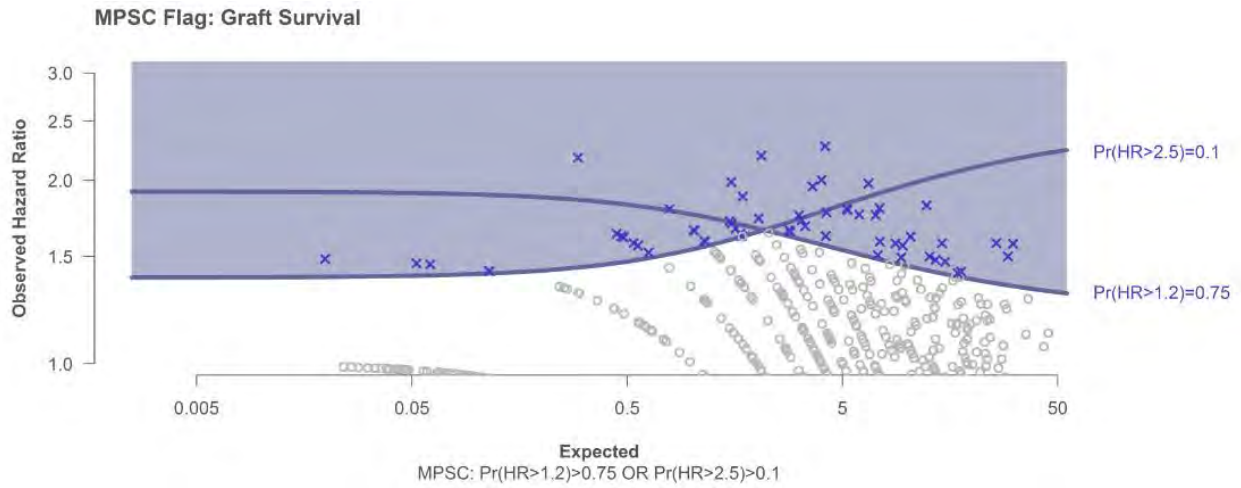


The MPSC expects a similar phenomenon when the proposed criteria are implemented. It would be expected that a certain percentage of programs identified each cycle will have been identified in a previous cycle and under review or recently released. In addition, there could be a small number of programs that meet the criteria for more than one metric during a particular cycle.

[39] Salkowski N, Snyder JJ, Zaun DA, Leighton T, Edwards EB, Israni AK, et al. A scientific registry of transplant recipients bayesian method for identifying underperforming transplant programs. *AJT.* 2014; 14: 1310-1317.
[40] Data based on an evaluation of the Spring 2020 SRTR MPSC reports presented by UNOS staff at May 7, 2021 MPSC Performance Monitoring Enhancement Subcommittee meeting.

Once the MPSC determined the new process should identify no more than the number of total "flags" under the current system, the MPSC considered whether separate criteria should be established for smaller volume programs or for pediatric transplants. Although the use of the Bayesian methodology improves the ability of boundaries to identify potentially underperforming medium and small volume programs, the ability to identify potentially underperforming small volume programs decreases as the probability (or certainty) that a program will be above a particular rate ratio or hazard ratio increases.[41] The current MPSC boundaries for 1-year post-transplant survival address this concern by including one boundary with a higher probability (greater than 75% probability that a program's patient or graft survival hazard ratio is greater than 1.2) and a second boundary with a much lower probability (greater than 10% probability that the hazard ratio is greater than 2.5). These criteria result in boundaries that are sloped as illustrated in **Figure 6** below:

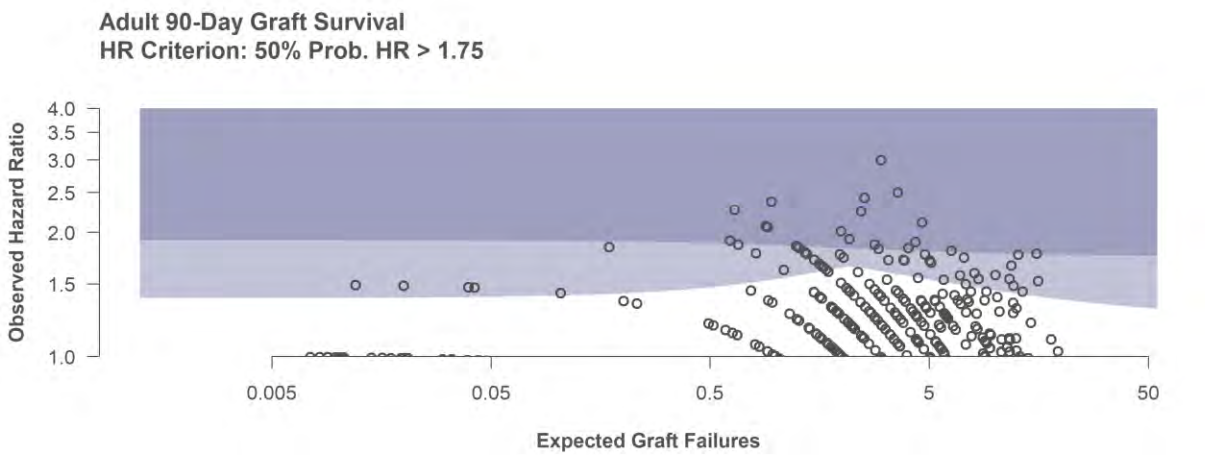
Figure 6: Plot of Current MPSC Post-Transplant Graft Survival Criteria[42]



Instead of creating separate criteria to capture smaller volume programs, the MPSC is proposing criteria that includes a 50% probability that a program is above, or below for offer acceptance, a certain rate ratio or hazard ratio for each metric. The 50% probability flattens the slope to reduce the effect of transplant volume size, waiting list size or number of offers on the process for identification of potentially underperforming programs. Using the 90-day graft survival proposed boundaries as an example, the slope of the proposed boundary is illustrated in the plot below. **Figure 7** below illustrates the proposed boundary for adult transplants in dark purple with the current MPSC boundaries superimposed in lighter purple.

[41] Salkowski N, Snyder JJ, Zaun DA, Leighton T, Edwards EB, Israni AK, et al. A scientific registry of transplant recipients Bayesian method for identifying underperforming transplant programs. *AJT.* 2014; 14: 1310-1317.
[42] Scientific Registry of Transplant Recipients. MPSC: Considerations in choosing a 'good' metric [presentation to MPSC November 5, 2019]. Available upon request.

Figure 7: Plot of Proposed Adult 90-Day Graft Survival Boundary[43]



Both of these figures contain circles for only those programs that are above the hazard ratio of 1.0, the hazard ratio at which programs are performing as expected.

The MPSC proposes separate boundaries for adult and pediatric transplants. The SRTR produces separate models for evaluation of adult and pediatric transplants.[44] Due to the overall lower volume and lower number of events for pediatric transplants, the level of certainty about the results for pediatric programs is lower; therefore, the hazard ratios for the pediatric boundaries for the post-transplant 90-day graft survival and 1-year graft survival conditional on 90 day graft survival are slightly lower and the rate ratio for offer acceptance is slightly higher than the proposed boundaries for adult transplants. Separate boundaries for adult and pediatric transplants was supported in public comment.

Finally, the MPSC considered how the "flags" should be distributed across the four metrics. The MPSC determined that the appropriate distribution would be a 50/50 split of the total number of "flags" across all organ types between the pre-transplant and post-transplant metrics. The MPSC believes that the pre-transplant and post-transplant outcomes are of equal importance to the patient experience and therefore, a 50/50 split is appropriate. Additionally, the requested number of "flags" for pre-transplant and post-transplant outcomes should be distributed across all organs so the resulting reviews would be concentrated where the most variation from the average exists.

Following determination of these parameters for the boundaries, the MPSC asked the SRTR to perform a data analysis that would produce optimal boundaries for each metric and identify the desired number of programs. The SRTR developed a tool for the MPSC to consider various boundaries, including the optimal boundaries that would identify the requested number and distribution of "flags," and to evaluate program data for programs that would likely be identified for review under the various boundaries.[45] MPSC members were able to use their clinical and subject matter expertise to review the relevant data for the programs identified, as well as those that fell immediately below the boundary and

[43] Scientific Registry of Transplant Recipients. Algorithm Explorer created for use by MPSC Performance Monitoring Enhancement Subcommittee. https://tools.srtr.org/Aggregate_Algorithm_Explorer/. Accessed June 28, 2021.
[44] Scientific Registry of Transplant Recipients. Technical Methods for the Program Specific Reports. https://www.srtr.org/about-the-data/technical-methods-for-the-program-specific-reports/. Accessed June 28, 2021.
[45] Scientific Registry of Transplant Recipients. Algorithm Explorer created for use by MPSC Performance Monitoring Enhancement Subcommittee. https://tools.srtr.org/Aggregate_Algorithm_Explorer/. Accessed June 28, 2021.

would be captured by alternative criteria. The MPSC, through this analysis, was able to determine if the proposed boundaries appropriately captured programs that were significant outliers and likely in need of performance improvement assistance in order to avoid a potential risk to patient health and public safety and whether the criteria failed to capture programs that raised concerns.

The MPSC reviewed and discussed the results of public comment regarding the development of criteria and the number of programs identified and concluded the public sentiment supports sending the proposal to the Board with no changes to these topics.

Adult Criteria

The boundaries proposed for programs that perform adult transplants are:

> 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 (waitlist 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 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.
> 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 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.

For pre-transplant mortality (waitlist mortality), 90-day graft survival and 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival, the rate or hazard ratio for worse than average performance is greater than 1.0. As explained previously, unlike heart, kidney, liver and lung, pancreas transplant programs will be evaluated based on 90-day post-transplant patient survival and one year post-transplant patient survival conditional on 90 day post-transplant patient survival because there is no current SRTR pancreas post-transplant graft survival model. For offer acceptance, the rate ratio for worse than average performance is less than 1.0. Therefore, for offer acceptance, a program with an offer acceptance rate ratio of 0.25 would be identified for review based on the criteria of a 50% probability that the offer acceptance rate ratio is less than 0.30.

The application of these criteria to the SRTR Spring 2020 Program Specific Report (PSR) data would result in a total of 62 adult flags for heart, kidney, liver and lung, compared to an average 68.5 adult flags for heart, kidney, liver and lung 1-year post-transplant patient and graft survival only over four reporting cycles (Spring 2019, Fall 2019, Spring 2020 and Fall 2020). **Table 2** below provides the breakdown of transplant programs identified by metric and organ type for heart, kidney, liver and lung.

Table 2: Number of Programs Identified for Adult Transplants Outcomes by the Proposed Metrics by Metric and Organ Type Using Data from Spring 2020 SRTR PSR.

Adult Proposed Boundaries	Heart	Kidney	Liver	Lung	Total
Waiting List Mortality - 50% Probability RR > 1.75	5	0	3	5	**13**
Offer Acceptance – 50% Probability RR < 0.30	1	6	5	2	**14**
90-day Graft Survival – 50% Probability HR > 1.75	3	10	4	2	**19**
Conditional 1-year Graft Survival – 50% Probability HR > 1.75	3	9	1	3	**16**
Total	**12**	**25**	**13**	**12**	**62**

At the time of the MPSC evaluation of the proposed criteria (April 2021), there were a total of 590 active heart, kidney, liver and lung transplant programs. A total of 53 active programs, or about 9% of programs, are identified by the 62 flags. About 91% of heart, kidney, liver and lung programs that perform adult transplants would not receive an inquiry from the MPSC under these criteria.

- Both post-transplant graft survival metrics combined would identify approximately 4.4% of heart, kidney, liver and lung programs that perform adult transplants.
- For waiting list mortality, approximately 2.2% of heart, kidney, liver and lung programs that perform adult transplants would be identified, so close to 98%, the overwhelming majority of heart, kidney, liver and lung programs, would not be identified as an outlier on waitlist mortality.
- The numbers for offer acceptance are the same as waitlist mortality.

The variation in the number of organ programs identified by each metric is due to level of variability of program performance on the metric for each organ. Lower variability among organ programs for a particular metric results in fewer outliers. For example, lack of significant variability in the waitlist mortality performance of kidney programs results in zero kidney programs being identified for waitlist mortality or heart transplant programs overall have a much higher offer acceptance rate so only one heart transplant program was identified for organ offer acceptance.

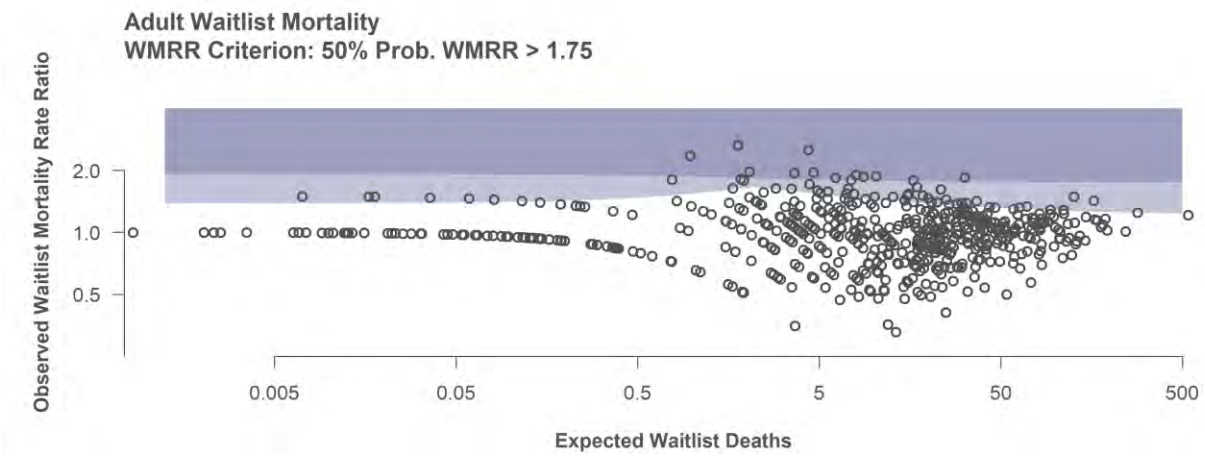
The application of these criteria to the SRTR Spring 2020 Program Specific Report (PSR) data would result in a total of seven adult flags for pancreas, compared to an average six adult flags for pancreas over four reporting cycles (Spring 2019, Fall 2019, Spring 2020 and Fall 2020) under the current performance criteria. The seven pancreas programs include three identified for waiting list mortality, four for offer acceptance, zero for 90 day patient survival and zero for conditional 1 year patient survival.

The following plots of the boundaries for each metric provide a visual representation of the level of underperformance that would result in being identified for MPSC performance review. Tables of the data for programs identified by each of the four metrics can be found in **Appendix A**.

Adult Waitlist Mortality

Figure 8 below includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if current MPSC criteria were used for waitlist mortality. An observed hazard ratio of 1.0 is average or performing as expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

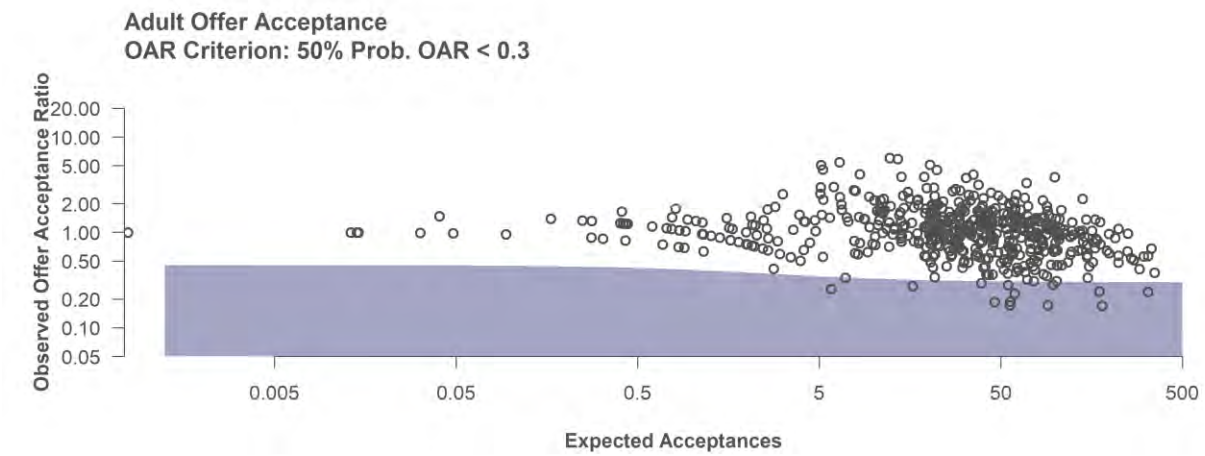
Figure 8: Plot of Proposed Adult Waitlist Mortality Boundary



Adult Offer Acceptance

Figure 9 below includes a circle for all heart, kidney, liver, and lung programs. The purple shaded area is the proposed boundary. An observed hazard ratio of 1.0 is average or performing as expected, programs above 1.0 are performing better than average, and programs below 1.0 are performing worse than average.

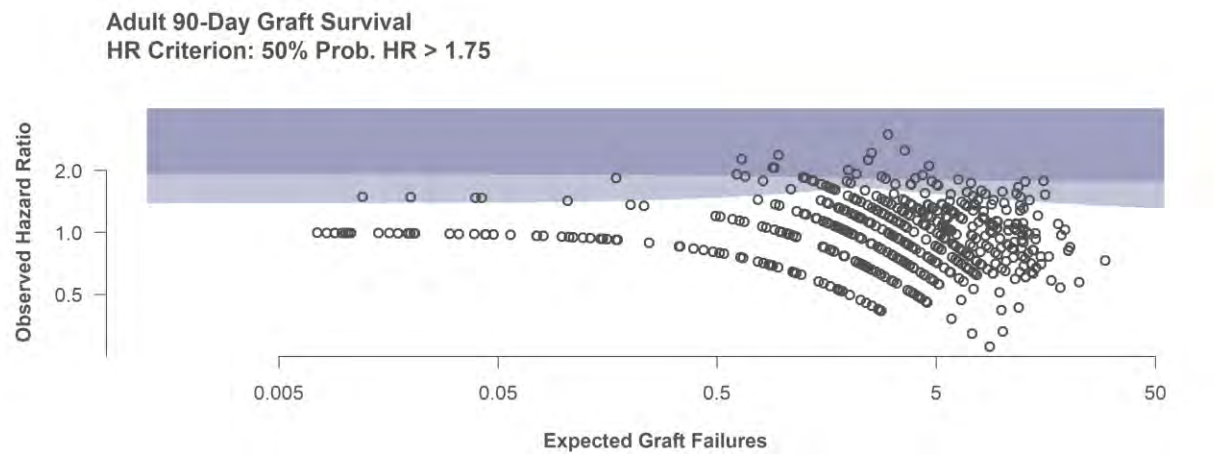
Figure 9: Plot of Proposed Adult Offer Acceptance Boundary



Adult 90-day Graft Survival

Figure 10 below includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if the current MPSC criteria was applied to 90-day graft survival. An observed hazard ratio of 1.0 is average or performing as expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

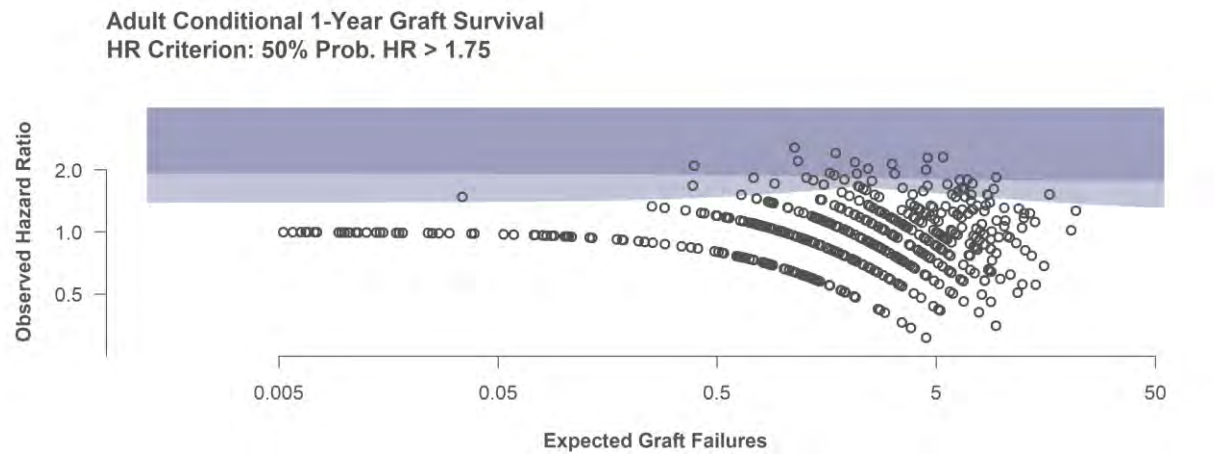
Figure 10: Plot of Proposed Adult 90-Day Graft Survival Boundary



Adult 1-year Post-transplant Graft Survival Conditional on 90-day Post-transplant Graft Survival

Figure 11 below includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if the current MPSC criteria was applied to 1-year conditional on 90-day post-transplant graft survival. An observed hazard ratio of 1.0 is average or performing as expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

Figure 13: Plot of Proposed Adult 1-year Post-Transplant Graft Survival Conditional on 90-day Graft Survival



Pediatric Criteria

The boundaries proposed for heart, kidney, liver and lung programs that perform pediatric transplants are:

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 (waitlist 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.

The pediatric boundary for pre-transplant (waitlist) mortality is the same as the adult boundary. For the other three metrics, the pediatric boundary is set slightly lower for the post-transplant graft survival metrics and slightly higher for the offer acceptance metric. For waitlist mortality, 90-day graft survival and 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival, the rate or hazard ratio for worse than average performance is greater than 1.0 where for offer acceptance, the rate ratio for worse than average performance is less than 1.0. Therefore, for offer acceptance, a program with an offer acceptance rate ratio of 0.25 would be identified for review based on the criteria of a 50% probability that the offer acceptance rate ratio is less than 0.35.

No criteria are proposed for pancreas pediatric transplants due to the low volume of pancreas pediatric candidates and transplants nationwide. The SRTR does not produce data for pancreas pediatric post-transplant patient survival because there are too few pancreas pediatric transplants and pediatric recipient deaths to calculate meaningful statistics. In 2020, there were 23 pancreas and kidney/pancreas pediatric transplants nationwide with four deaths reported as of July 23, 2021. In addition, due to the low volume of pancreas pediatric candidates, waitlist mortality and offer acceptance rates are available for a very small number of programs. On July 25, 2021, there were 51 pancreas pediatric candidates on the U.S. waiting list at approximately 11 transplant programs.

The application of these criteria to the SRTR Spring 2020 PSR data would result in a total of 29 pediatric flags for heart, kidney, liver and lung, compared to an average 27 flags for heart, kidney, liver and lung under the current 1-year post-transplant patient and graft survival criteria over four reporting cycles (Spring 2019, Fall 2019, Spring 2020 and Fall 2020). **Table 3** below provides a breakdown by metric and organ type for heart, kidney, liver and lung.

Table 3: Number of Programs Identified for Pediatric Transplants Outcomes by the Proposed Metrics by Metric and Organ Type Using Data from Spring 2020 SRTR PSR.

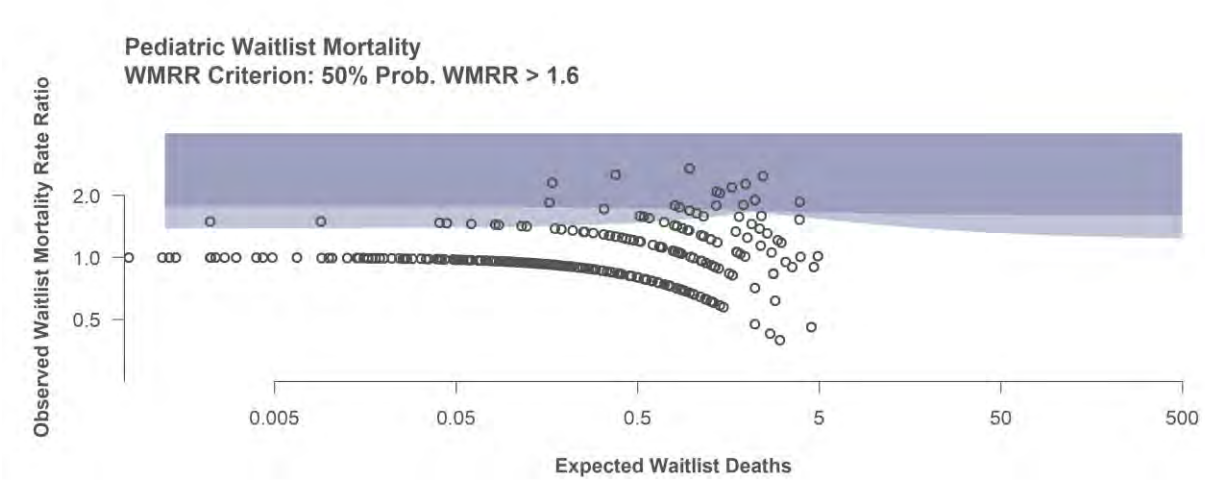
Pediatric Proposed Boundaries	Heart	Kidney	Liver	Lung	Total
Waiting List Mortality - 50% Probability RR > 1.75	8	0	2	0	**10**
Offer Acceptance – 50% Probability RR < 0.35	2	3	0	1	**6**
90-day Graft Survival – 50% Probability HR > 1.60	4	2	1	1	**8**
Conditional 1-year Graft Survival – 50% Probability HR > 1.60	1	1	2	1	**5**
Total	**15**	**6**	**5**	**3**	**29**

The following plots of the boundaries for each metric provide a visual representation of the level of underperformance that would result in being identified for MPSC performance review. Tables of the data for programs identified by each of the four metrics can be found in **Appendix A**.

Pediatric Waitlist Mortality

Figure 12 below includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if current MPSC criteria were used for waitlist mortality. An observed hazard ratio of 1.0 is average or performing as expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

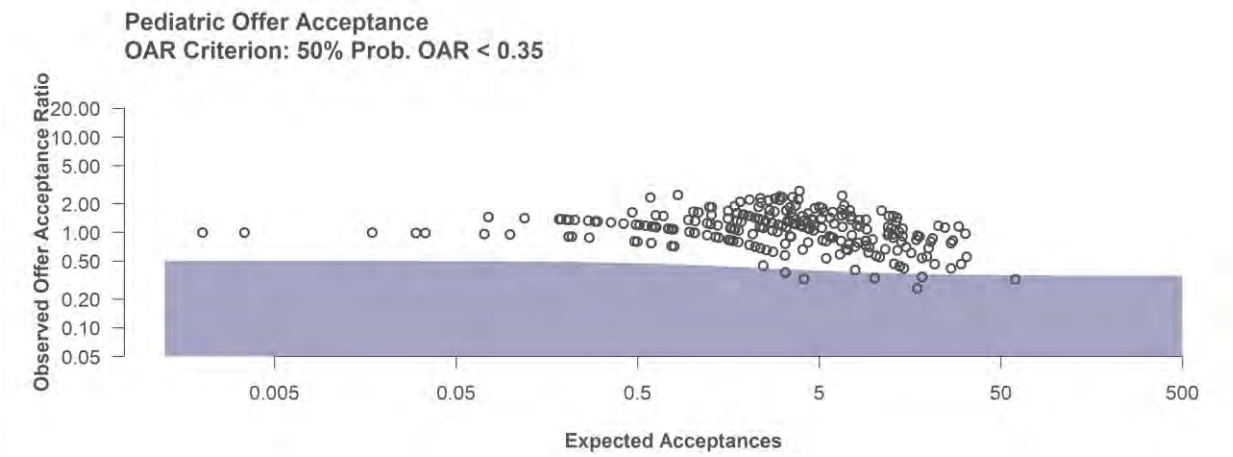
Figure 12: Plot of Proposed Pediatric Waitlist Mortality Boundary



Pediatric Offer Acceptance

The below **Figure 13** includes a circle for all heart, kidney, liver, and lung programs. The purple shaded area is the proposed boundary. An observed hazard ratio of 1.0 is average or performing as expected, programs above 1.0 are performing better than average, and programs below 1.0 are performing worse than average.

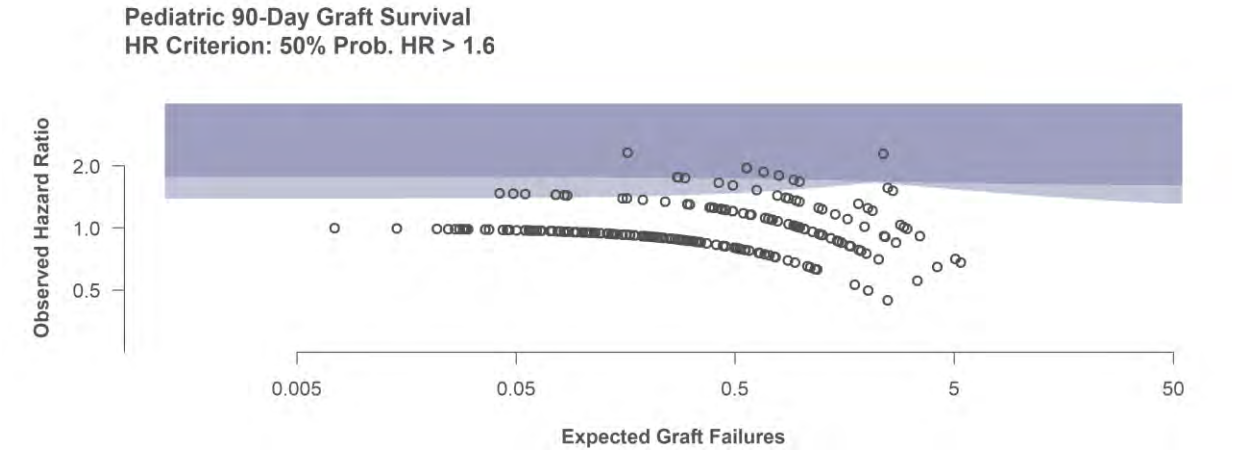
Figure 13: Plot of Proposed Pediatric Offer Acceptance Boundary



Pediatric 90-day Graft Survival

The below **Figure 14** includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if current MPSC criteria were used for 90-day graft survival. An observed hazard ratio of 1.0 is average or performing as expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

Figure 14: Plot of Proposed Pediatric 90-day Graft Survival Boundary



Pediatric 1-year Post-transplant Graft Survival Conditional on 90-day Post-transplant Graft Survival

The below **Figure 15** includes a circle for all heart, kidney, liver, and lung programs. The dark purple shaded area is the proposed boundary and for comparison purposes, the dark and light purple combined shaded area would be the boundary if current MPSC criteria were used for 1-year graft survival conditional on 90-day graft survival. An observed hazard ratio of 1.0 is average or performing as

expected, programs below 1.0 are performing better than average, and programs above 1.0 are performing worse than average.

Figure 15: Plot of Proposed Pediatric 1-year Post-Transplant Graft Survival Conditional on 90-day Graft Survival

Review of Programs Identified in MPSC Intervention zone

Transplant program identification using the above criteria for the MPSC intervention or "red" zone does not in and of itself indicate that a transplant program poses a risk to patient health or public safety. The criteria are designed to trigger a MPSC inquiry and interaction with the transplant program to gather information to determine if further interaction is needed to help the transplant program avoid risk to patient health or public safety as described in more detail in the *Member Compliance* section below.

Addition of Peer Visit Section

The MPSC uses peer visits for all manner of performance and compliance issues as a tool to help transplant programs improve. Although there is a current reference in Appendix D to peer visits, the OPTN bylaws have not previously included a description of the peer visit process and member expectations. The MPSC is taking this opportunity to include language in the bylaws describing peer visits, thereby providing more transparency to members on the role of peer visits in MPSC reviews. The MPSC proposes the inclusion of the peer visit section in Appendix M: *Reviews and Actions* since this placement is consistent with the description of other MPSC review tools such as informal discussions. Other administrative revisions to Appendix M: *Reviews and Actions* are proposed in order to ensure consistency with the proposed revisions to Appendix D.13.A and the new proposed peer visit bylaw section.

Definitions Revisions

This proposal includes a few administrative revisions to Appendix N: *Definitions*. The MPSC proposes to remove definitions of two defunct standing MPSC subcommittees, the Performance Analysis and Improvement Subcommittee (PAIS) and the Policy Compliance Subcommittee (PCSC), from the OPTN bylaw definitions. These two subcommittees were disbanded in 2018. In addition, the MPSC is proposing revisions to the definition of the Scientific Registry of Transplant Recipients (SRTR) definition to remove

specific references to the patient and graft survival rates and to mirror language from the background information on the Mission, Vision and Values on the SRTR website.

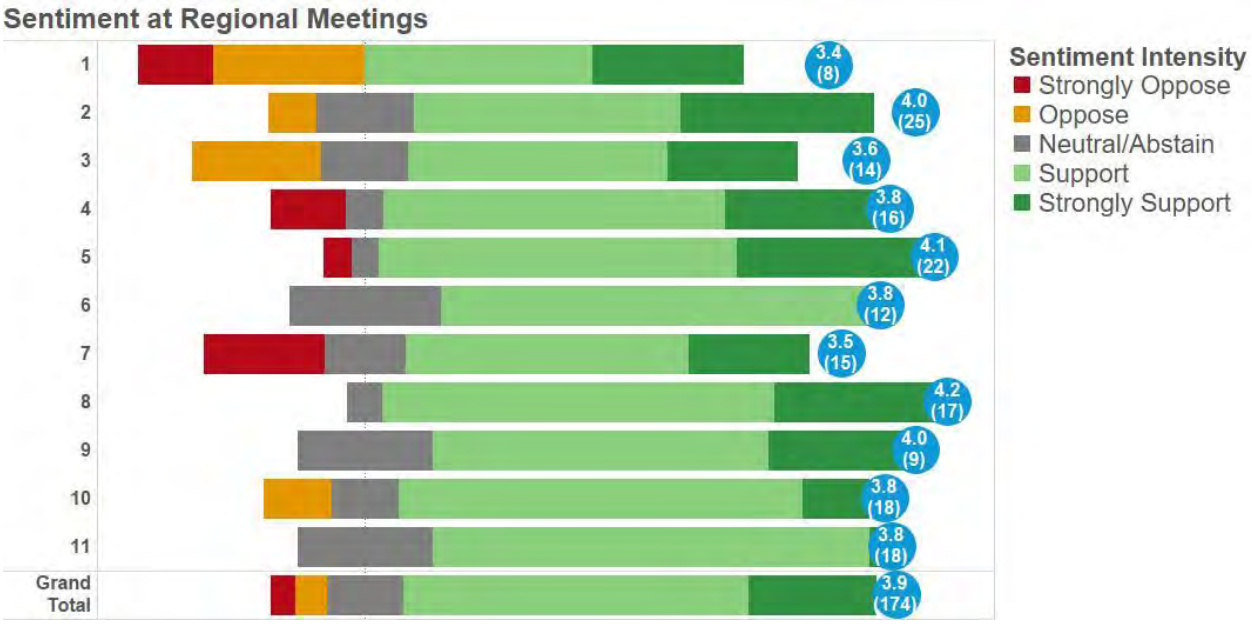
Post public comment, the MPSC proposes the insertion of descriptions of the four proposed metrics into Appendix N: *Definitions*. The MPSC believe this would provide more transparency and promote better understanding of the measures proposed for evaluation of transplant program performance.

Overall Sentiment from Public Comment

The proposal was available for public comment from August 3 through September 30, 2021. During that time, it received 233 responses. The MPSC requested specific feedback on the potential future use of a longer-term period prevalent survival metric, types of assistance that would be helpful to programs that fall within the performance improvement zone and education and resources needed to respond to new metrics and become comfortable with risk adjustment. Following is a summary of the overall sentiment for the proposal, as well as a summary of the primary themes of public comment received.

The proposal was supported across all Regions, with an average sentiment score of 4.2/5 on the Likert sentiment scale. **Figure 16** shows the sentiment by Region, which was supportive overall.

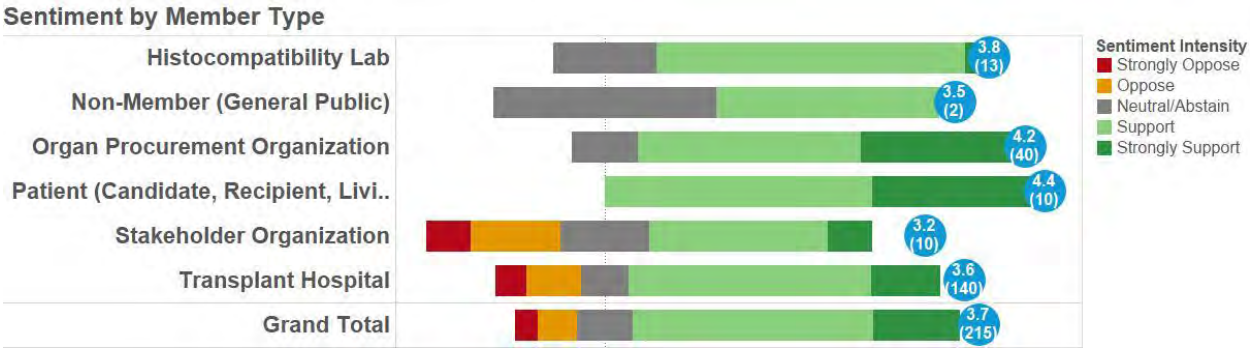
Figure 16: Sentiment by Region[46]



[46] Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 17 shows the sentiment received at regional meetings and through the OPTN Public Comment website by member type, with the highest support coming from patients and organ procurement organizations (OPO).

Figure 17: Sentiment by Member Type[47]



The major themes on which the OPTN received feedback were:

- Use of the waitlist (pre-transplant) mortality rate ratio for evaluation of transplant programs may result in risk averse listing behavior generally and may not be appropriate for kidney transplant programs that often do not manage patients on the waiting list.
- Use of the organ offer acceptance rate ratio for evaluation of transplant programs was supported by the majority of comments but some expressed concern that it would discourage use of broad acceptance criteria reducing the ability of programs to evaluate each organ to maximize patient opportunity for transplant.
- Use of risk adjusted metrics and the development of criteria, including the number of programs identified. The majority of comments supported the use of risk adjusted metrics. Some comments suggested use of an unadjusted fixed floor or raised concerns about risk factors that are not currently represented in the SRTR metric models. Comments were received raising concerns about too many programs being identified and too few as well as a concern about the focus on the number of programs being identified rather than on ensuring the identification of all programs with suboptimal performance.

The American Society of Transplantation (AST) expressed a neutral sentiment and submitted comment stating that it is supportive of moving beyond one-year outcomes used to assess transplant programs but had considerable comment on the proposal as written. The AST raised concerns as stated in the themes above with the use of waitlist mortality and generally supported the use of offer acceptance with minimal concerns about the inclusion of all offer refusals while recognizing that the new offer filters may alleviate these concerns. The AST supported use of both of the proposed post-transplant graft survival metrics. While the AST supported use of risk adjustment, they noted that some relevant risk factors may not be accounted for in the risk adjustment models. The AST also questioned the adjustment of the thresholds to identify a comparable number of programs. The AST's Transplantation Community Advisory Committee, which is comprised of transplant recipients, supported the use of a longer term post-transplant outcome measure and noted that the proposal sets a low post-transplant graft survival bar that nearly all transplant programs are able to meet reliably rather than setting boundaries that would encourage performance growth and positive change to challenge the status quo

[47] Ibid.

in transplant survival. The Advisory Committee also suggested additional patient-centric measures for consideration and requested that MPSC data be made available to the public.

The American Society of Transplant Surgeons (ASTS) strongly opposes the proposal. The ASTS expressed concern that more metrics may hamper the transplant community's goal to increase transplants. The ASTS suggested continued use of only the one-year post-transplant patient and graft survival with a change to an unadjusted fixed floor criteria based on the survival rate for alternative therapies. The ASTS mentioned the possibility of application of a secondary analysis applying limited risk adjustment. In the alternative, the ASTS raised similar concerns to other comments about the proposed pre-transplant metrics. Finally, the ASTS was concerned that too many programs would be identified for performance review under this proposal.

The Association of Organ Procurement Organizations (AOPO) strongly supports the proposal stating that both of the proposed pre-transplant metrics align with the OPO performance metrics and will facilitate significant system wide performance improvement. AOPO noted that the addition of the waitlist mortality metric is important and has the potential to decrease organ discards as the system shifts to a patient-centric understanding of risk-benefit which must evaluate the risk to a candidate of receiving an organ versus the risk to a candidate of not receiving the organ offered. AOPO also supports the inclusion of the offer acceptance metric that will incentivize best practices regarding use of screening criteria and offer filters which will provide needed efficiency improvement in the context of broader distribution and the increasing number of organs being recovered from older and medically complex donors. AOPO did suggest that the MPSC reconsider use of transplant rate as a performance measure, if not for transplant programs, as a shared performance metric to evaluate both OPOs and transplant programs.

The feedback received on the themes and the concerns and suggestions raised by the societies are addressed in detail in the applicable sections of the description of the proposal above.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal for the Board consideration 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."[48] 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;

[48] 42 C.F.R. §121.10 (b)(1)(iii)

- 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.

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 BOD; and
- refer members to the Secretary when federal sanctions may be warranted.[49]

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. To efficiently identify and evaluate the transplant programs most likely in need of assistance to avoid potential risks to patient health and public safety, the MPSC proposes these evidenced-based boundaries for the performance review metrics; programs that fall outside of a boundary will be required to participate in the performance review process.

OPTN Strategic Plan

1. *Increase the number of transplants:* The proposal improves the MPSC metrics and monitoring approach to transplant program performance review through the evaluation of multiple aspects of transplant program care including the new emphasis on pre-transplant waiting list management and offer acceptance and less emphasis on post-transplant outcomes that will encourage improvement in candidate survival to transplant, offer acceptance practices and system efficiency resulting in an increase in the number of transplants. The proposal also focuses on increased collaboration and performance improvement activities when assessing transplant program performance.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The proposal supports improvement of the waitlisted patient outcomes and transplant recipient outcomes through inclusion of waitlist (pre-transplant) mortality and offer acceptance and two post-transplant outcomes metrics to evaluate transplant program performance. MPSC evaluation, review and OPTN assistance provided to programs encourages programs to develop processes to improve the likelihood that waitlisted patients receive a transplant and have good post-transplant outcomes.
4. *Promote living donor and transplant recipient safety:* The proposal supports the promotion of transplant recipient safety through the establishment of appropriate criteria for identifying and providing assistance to programs that may pose a potential risk to patient health or public safety.

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

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplant hospital members will need to be familiar with the proposed new metrics for transplant program performance monitoring and the MPSC's review process. Transplant hospital members should review the data currently available for each transplant program via the member's secure SRTR site, to assess whether a program is likely to be identified for review once the proposal is implemented. Though the MPSC has not reviewed programs' pre-transplant data, programs' offer acceptance and waitlist mortality data are currently provided on the SRTR secure site for review by the program. Upon approval, members will continue to be able to access information on whether their programs meet MPSC criteria on the members' secure SRTR sites.

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 MPSC will use reports generated by the SRTR using models developed by the SRTR for all four transplant program metrics included in the proposal.

The MPSC is recommending that the proposed metrics be implemented based on the following timeline:

- 90-day graft survival and 1-year graft survival conditional on 90-day survival post-transplant outcomes criteria will be implemented in the first SRTR reporting cycle that occurs at least 6 months after approval by the OPTN Board of Directors.
- Offer acceptance criteria will be implemented in the SRTR reporting cycle that occurs at least 18 months after approval by the OPTN Board of Directors.
- Waitlist mortality criteria will be implemented in the SRTR reporting cycle that occurs at least 30 months after approval by the OPTN Board of Directors.

The OPTN will provide members with notice of pending implementation approximately 6 months prior to implementation to coincide with the release of the SRTR PSR that immediately precedes the effective date of use of the metric for MPSC review.

Because the MPSC's transplant program performance review process has historically focused on post-transplant patient and graft survival, the MPSC feels it is appropriate to replace the current 1-year patient and graft survival metrics with the proposed 90-day graft survival and 1-year-conditional-on-90-day graft survival metrics as soon as the SRTR is able to provide the updated reports to the MPSC. Once the new post-transplant metrics are implemented, the MPSC will release from review any program that is no longer identified under the new system. The MPSC will collaborate on a voluntary basis with any member released from review that requests further assistance. The MPSC will continue to monitor any program that was previously under review and is also identified for review under the new criteria.

The MPSC is recommending that the Board of Directors delay the implementation of the proposed pre-transplant metrics to allow programs time to better understand the metrics, review their applicable data and practices, and make changes as desired. Specifically, the pre-transplant metrics will not be implemented until at least one complete cohort has passed, after the OPTN Board of Directors approves the proposal. The organ offer acceptance metric is calculated using a 12-month interval, and is reported six months after conclusion of the 12-month interval. Therefore, the organ offer acceptance metric will be implemented no sooner than 18 months after approval by the OPTN Board of Directors. Similarly, the waitlist mortality metric is calculated using a 24-month interval and is also reported six months after the conclusion of the 24-month interval. The waitlist mortality metric will be implemented no sooner than 30 months after approval by the OPTN Board of Directors. This will ensure the MPSC will only evaluate programs based on transplant program performance using data collected after the OPTN Board of Directors has approved the proposed metrics.

Prior to implementation of the organ offer acceptance and pre-transplant (waitlist) mortality criteria, the OPTN will notify programs that would be identified by these criteria that the programs will be identified for review once the criteria are implemented. The OPTN may ask these programs to voluntarily provide information to the OPTN for use in evaluation of the criteria and for development of resource materials and appropriate areas of inquiry. The OPTN will also collaborate with high performing programs to identify effective practices and develop resources.

The OPTN will also develop education and resources to prepare MPSC members to review programs identified under the new criteria and promote consistency in performance reviews.

Prior to implementation, the OPTN will provide educational offerings to help programs understand how various scenarios may impact each metric, and how to find and interpret data available on the SRTR secure sites.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN and transplant hospitals, but it is not anticipated to have any fiscal impact on organ procurement organizations or histocompatibility laboratories.

Projected Impact on Transplant Hospitals

Transplant hospital members will need to be familiar with the proposed new metrics for transplant program performance monitoring and the MPSC's review process. Transplant hospital members should review the data currently available for each transplant program via the member's secure SRTR site, to assess whether a program is likely to be identified for review once the proposal is implemented. Though the MPSC has not reviewed programs' pre-transplant data, programs' offer acceptance and waitlist mortality data are already provided on the SRTR secure site. Upon approval, members will continue to be able to access information on whether their programs meet MPSC criteria on the members' secure SRTR sites.

Projected Impact on the OPTN

Member Quality supported the Membership and Professional Standard Committee (MPSC) in their proposal to establish a more comprehensive system that evaluates several parts of transplant program performance, rather than solely post-transplant metrics. The development of this process will allow for a more fair and accurate assessment of a transplant programs performance.

This will require a large number of implementation hours from Member Quality. These allow for the education of Member Quality staff, the updating of internal monitoring processes and documentation, and assistance in member outreach and education. In total, these amount to 2000 implementation hours. Communications will require 400 implementation hours to support these processes, as well as to address questions and create tool kits for members. Research and IT have no implementation hours, respectively.

Ongoing monitoring efforts by Member Quality are not anticipated to exceed the current performance monitoring for the first three years, especially since performance monitoring changes will be implemented in phases. A small increase of about 100 in annual hours may occur, related to Member Quality staff evaluation of the effectiveness of the monitoring changes over time and as a result of potential assistance requests from members in the yellow zone.

Post-implementation Monitoring

Member Compliance

While the metrics and criteria used to identify transplant programs for MPSC engagement would change under this proposal, the review and engagement process will not substantially change. The OPTN will continue to receive reports from the SRTR twice a year that assess each transplant program's performance against the new metrics and criteria and will use these reports to identify transplant programs for MPSC engagement. Member Quality staff will continue to send inquiries on behalf of the MPSC 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.

A performance improvement zone will be established operationally by the MPSC. The OPTN will make the performance improvement zone boundaries publicly accessible on its website. Programs that fall within the performance improvement zone will receive a letter informing the program that they are

trending towards the MPSC intervention zone; encouraging the program to evaluate their performance for areas of improvement, if they have not already done so; and offering performance improvement assistance from a catalog of services, if desired. A program that falls within the performance improvement zone will not be obligated to interact with the OPTN. Therefore, the criteria for this zone are not included in the proposal.

The assistance offered will be drawn from the OPTN Individualized Member Focused Improvement (IMFI) catalog of services including:

- Education and training services either remotely or on-site on various topics such as the UNet^{SM} Data Portal tool, root cause analysis and corrective action plan reviews, process mapping and change management
- Quality and performance improvement services such as process mapping, customized coaching sessions and guidance on PDSA worksheet
- Peer and subject matter expert engagements such as peer mentoring and connecting with other members to work together on similar issues.

The services available to members through the performance improvement zone and individual member requests will continue to develop and evolve.

Bylaw Evaluation

This bylaw will be formally evaluated at least annually post-implementation. Due to the staged implementation timeline and variations in the cohort periods, the evaluation metrics included in each annual evaluation report may vary. In addition to evaluating the effectiveness of this proposal to identify any needed adjustments as described below, the MPSC will continue to consider improvements to the transplant program performance review system through the consideration of new measures that may become available in the future or additional enhancements to the process for review and collaborative improvement assistance offered to OPTN members.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- Have the new criteria contributed to a change in the number of transplants?
- Have the new criteria affected transplant program listing practices?
- Have the new criteria contributed to a change in offer acceptance rates?
- Have the new criteria contributed to a change in waitlist mortality rates?
- Have the new criteria contributed to changes in the aforementioned metrics with respect to patient populations associated with risk (e.g., high-KDPI donors) or demographics (e.g., age, ethnicity)?
- Are the new criteria effective at identifying small volume transplant programs with potential patient health and public safety issues?

Does MPSC engagement result in sustained improvement in waitlist mortality, offer acceptance and 1-year post-transplant graft survival?

To help answer the above questions, the following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available for pre- and post-bylaw implementation.

National mean utilization through organ yield rates for each organ (Heart, Kidney, Liver, Lung and Pancreas) before and after implementation.

- Number of waiting list additions before and after implementation including:
  - National mean listing rate for each organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability across programs by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability based on risk stratification (e.g., MELD, dialysis time), and demographics (e.g., age, ethnicity)
- Offer Acceptance rates before and after implementation including:
  - National mean acceptance rate by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability across programs by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability based on risk stratification and demographics
  - Waitlist mortality rates before and after implementation including
  - National mean waitlist mortality rate by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability across programs by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability based on risk stratification and demographics
- Number of graft failures (or patient deaths for pancreas) during the first year post-transplant before and after implementation
  - National 1-year survival rates by organ transplanted (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability across programs by organ (Heart, Kidney, Liver, Lung and Pancreas)
  - Variability based on risk stratification and demographics

The MPSC will also evaluate the effectiveness of the criteria and the MPSC interactions with programs through monitoring of:

- Number of programs identified by each metric and the number of unique programs identified in each semiannual report
- Member feedback obtained during and following MPSC engagement
- Evaluation of improvement at programs with which the MPSC engaged and if that improvement was sustained following release from review
- Periodically review data of and collect information from programs that perform less than one transplant per month on average to evaluate the effectiveness of the criteria to identify potential issues at smaller volume programs and consider appropriate alternatives, if needed.

Though this proposal does not include any changes to data collection or recommendations for changes to the existing risk-adjustment models created by the SRTR, the MPSC intends to proactively collect and evaluate data that may help inform changes to those areas. Specifically, during each performance review, the MPSC will evaluate whether any data variables that are not currently collected or included in the risk-adjustment models seem to have affected program outcomes. The MPSC will include this analysis in its annual evaluation report.

Conclusion

In an effort to holistically evaluate transplant program performance, the MPSC proposes to use four separate metrics that each measure a distinct aspect of transplant program patient care – waitlist mortality rate measuring waiting list patient care, offer acceptance rate measuring offer acceptance practices, 90-day post-transplant graft survival measuring peri-operative care and 1-year post-transplant

graft survival conditional on 90-day graft survival measuring post-operative care. The MPSC chose the proposed metrics based on an evaluation that required each metric to measure aspects of care that are clearly within the authority of the OPTN; measure aspects of care that the transplant program can impact; have a clear desired outcome; not require the collection of new data or development of a new metric; be risk-adjusted; and incentivize behaviors that increase transplantation. Following public comment, the MPSC proposes the replacement of the term “waitlist mortality” with “pre-transplant mortality” due to a change in the term used for this metric by the Scientific Registry of Transplant Recipients (SRTR). The MPSC has also inserted descriptions of the proposed metrics in Appendix N: *Definitions*. These changes will ensure consistency and transparency to the community regarding the metric that is being used to evaluate transplant programs.

The boundaries proposed for the metrics are focused on identifying clinically meaningful outlier transplant programs that potentially pose a risk to patient health or public safety. Based on the differences in transplant volume and number of events in pediatric transplant, the MPSC proposes separate slightly lower pediatric boundaries for three of the four metrics. The MPSC asserts that this proposal improves upon the current performance evaluation system using reliable, available metrics that measure multiple aspects of transplant program patient care to create a better, more holistic transplant program performance monitoring system.

Additionally, the proposal includes a new section in Appendix M, *Review and Actions* that codifies the current peer review process. Other administrative changes have been made to Appendix M, *Review and Actions* to ensure consistency with the new peer visit section and Appendix N: *Definitions* to delete definitions for two defunct MPSC standing subcommittees and update the definition for the SRTR.

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.

Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

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 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.
   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 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 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*.

~~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 M: Reviews and Actions

M.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.

M.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.

M.~~8~~9 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.*

M.~~14~~15 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. ~~4.~~ The hearing

Appendix N: 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.

Appendix A

Tables A-1 through A-8 below provide data about programs that would have been identified by the proposed metrics using the SRTR Spring 2020 PSR data set. This data was examined by the MPSC to determine if the proposed metrics identify significant outliers that are likely in need of performance improvement assistance in order to avoid a potential risk to patient health and public safety.

Table A-1: Data for programs identified by proposed adult criteria for waitlist mortality

Number	Organ	Person Years	Observed	Expected	WM Rate Ratio
1	HR	24.01	8	1.79	2.64
2	HR	70.32	14	4.37	2.51
3	HR	10.17	5	0.97	2.35
4	LU	24.13	6	2.06	1.97
5	LU	29.66	11	4.65	1.95
6	LU	43.68	9	3.66	1.94
7	LU	90.23	17	8	1.9
8	LI	77.78	21	10.3	1.87
9	LI	78.61	18	8.75	1.86
10	LU	248.43	60	31.66	1.84
11	HR	89.24	13	6.16	1.84
12	HR	82.05	15	7.49	1.79
13	LI	101.65	31	16.48	1.79

Table A-2: Data for programs identified by proposed adult criteria for offer acceptance

Number	Organ	Offers	Observed	Expected	OA Ratio
1	KI	12953	29	180.72	0.17
2	KI	4970	8	56.21	0.17
3	LI	1266	14	90.85	0.17
4	LU	1041	7	46.31	0.19
5	KI	1913	9	56.53	0.19
6	LI	1269	12	59.7	0.23
7	KI	68962	75	323.66	0.24
8	KI	3556	40	174.03	0.24
9	LI	26	0	5.83	0.26
10	LU	352	3	16.36	0.27
11	LI	1021	14	54.94	0.28
12	HR	1674	26	97.1	0.28
13	LI	349	10	39.12	0.29
14	KI	2825	1	6.96	0.33

Table A-3: Data for programs identified by proposed adult criteria for 90-day graft survival

Number	Organ	Transplants	Observed	Expected	Hazard Ratio
1	KI	140	13	3.01	2.99
2	KI	120	12	3.6	2.5
3	LI	59	9	2.54	2.43
4	KI	53	5	0.95	2.37
5	KI	41	4	0.65	2.27
6	HR	53	8	2.44	2.25
7	KI	198	12	4.63	2.11
8	LU	21	4	0.9	2.07
9	KI	44	4	0.91	2.06
10	KI	101	6	1.97	2.01
11	KI	86	6	2.16	1.93
12	HR	11	3	0.62	1.91
13	KI	200	10	4.33	1.9
14	LI	62	7	2.82	1.87
15	HR	28	4	1.23	1.86
16	LU	94	9	4.01	1.83
17	LI	60	7	2.93	1.82
18	LI	127	13	6.3	1.81
19	KI	633	29	15.44	1.78

Table A-4: Data for programs identified by proposed adult criteria for 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival

Number	Organ	Transplants	Observed	Expected	Hazard Ratio
1	KI	75	6	1.12	2.56
2	KI	107	7	1.74	2.41
3	LI	192	15	5.37	2.31
4	HR	166	13	4.57	2.28
5	LU	23	5	1.17	2.21
6	LU	43	7	2.13	2.18
7	LU	70	9	3.15	2.14
8	KI	24	3	0.39	2.09
9	KI	142	7	2.44	2.03
10	KI	248	11	4.49	2
11	KI	86	5	1.63	1.93
12	HR	80	6	2.18	1.91
13	KI	200	8	3.23	1.91
14	HR	59	5	1.71	1.89
15	KI	506	19	9.4	1.84
16	KI	482	14	6.93	1.79

Table A-5: Data for programs identified by proposed pediatric criteria for waitlist mortality

Number	Organ	Person Years	Observed	Expected	WM Rate Ratio
1	HR	8.56	6	0.97	2.7
2	HR	9.03	4	0.38	2.52
3	HR	24.97	9	2.45	2.47
4	HR	2.74	3	0.17	2.3
5	LI	39.19	7	1.96	2.27
6	HR	24.99	6	1.65	2.19
7	HR	11.77	5	1.36	2.08
8	HR	12.85	5	1.42	2.05
9	HR	13.54	6	2.21	1.9
10	LI	77.19	9	3.92	1.86

Table A-6: Data for programs identified by proposed pediatric criteria for offer acceptance

Number	Organ	Offers	Observed	Expected	OA Ratio
1	KI	191	3	17.34	0.26
2	HR	621	18	60.03	0.32
3	LU	133	0	4.14	0.33
4	KI	134	2	10.11	0.33
5	HR	123	5	18.39	0.34
6	KI	41	0	3.25	0.38

Table A-7: Data for programs identified by proposed pediatric criteria for 90-day graft survival

Number	Organ	Transplants	Observed	Expected	Hazard Ratio
1	KI	16	3	0.16	2.31
2	LI	40	8	2.37	2.29
3	KI	55	3	0.56	1.95
4	HR	14	3	0.57	1.95
5	HR	17	3	0.67	1.87
6	HR	20	3	0.79	1.79
7	HR	9	2	0.27	1.76
8	LU	11	2	0.28	1.76

Table A-8: Data for programs identified by proposed pediatric criteria for 1-year post-transplant graft survival conditional on 90-day post-transplant graft survival

Number	Organ	Transplants	Observed	Expected	Hazard Ratio
1	HR	18	3	0.52	1.98
2	LU	2	2	0.06	1.94
3	LI	2	2	0.09	1.91
4	KI	44	2	0.19	1.82
5	LI	58	3	0.86	1.75