ASTS
American Society of Transplant Surgeons

ASTS Recommendations for Optimization of Transplant Center Assessment

Approved by ASTS Council January 12, 2021.

Executive Summary

Over the past several years, it has become clear that current patient and graft survival metrics disincentivize Transplant Center (TC) acceptance of organs at risk of discard and the transplantation of older and less healthy recipients. By discouraging aggressive organ acceptance practices, the current TC metrics create irreconcilable incentives for OPOs and TCs and limit the number of transplants performed.

While the Centers for Medicare and Medicaid Services (CMS) has discontinued the use of patient and graft survival metrics as a condition of TC recertification, graft and patient survival-related metrics continue to be used by the Organ Procurement and Transplantation Network's (OPTN) Membership and Professional Standards Committee (MPSC) to trigger TC performance evaluation that may result in the imposition of public sanctions and by the Scientific Registry of Transplant Recipients (SRTR) for the purposes of TC public star ratings. A growing consensus supports the necessity of modifying TC outcomes metrics**.**

It is critical that any new metrics be developed with the input of the entire transplant community and include input from associations representing transplant surgeons, transplant physicians, OPOs, patient organizations and other affected stakeholders. While metrics used to trigger TC review by the MPSC will be implemented by the OPTN, and while public metrics will be calculated by the SRTR, organizations participating in the development of these metrics should not be limited to the OPTN and SRTR. It is critical that other stakeholders participate in the development of new metric regimes, rather than being relegated to token involvement during the public comment process. All the organizations whose members ultimately will be affected by new metrics should be allowed to participate meaningfully in their development. Without full participation of organizations representing the transplant community, new metrics are unlikely to be fully accepted. Token involvement of the stakeholders central to the initiatives and operations needed to increase the numbers of transplants performed will likely produce suboptimal results. Meaningful involvement in new metrics and flagging parameters by all stakeholders, including the ASTS, is likely to decrease the unanticipated consequences of these inevitably complex policy decisions and maximize the likelihood of successful implementation.

This White Paper outlines ASTS' position on the development of new TC metrics and includes the following recommendations:

- TC star ratings based on patient and graft survival should be eliminated. The objective of any new comparative ratings or other public metrics should be designed to meet the informational needs of potential transplant recipients.

- SRTR Provider Specific Reports (PSRs) should contain data comparing TC outcomes with the outcomes of the primary treatment alternative for end stage organ failure (such as dialysis, in the case of renal transplantation).
- Eliminate the current outcomes triggers for MPSC performance review of TCs and substitute a confidential peer review process designed to encourage TCs to increase the number of transplants performed without falling below established professionally acceptable outcomes parameters.
    - The current patient and graft survival metrics used to flag TCs for MPSC performance review should be replaced by a metric specifying a minimal fixed survival floor, similar to a pass/fail system, with the standard established at a level that encourages more aggressive utilization of organs at risk of discard.
    - We note that the MPSC has made an overt and laudable effort to make the focus of member engagement quality improvement rather than viewing its primary role as meting out punishment to members. This change has been salutary for members, the patients they serve and for the MPSC. We advocate that the MPSC continue this cultural change focusing on promoting quality improvement.
- The development of metrics focused on the long-term effects of transplantation should be developed to facilitate research in the field but should not be used as TC performance outcome flagging.

ASTS looks forward to participating with other organizations representing the transplant community in establishing new measures of TC performance designed to meet the needs of transplant recipients and donors.

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Introduction

The selection of appropriate metrics for evaluating TC performance has been the focus of considerable attention since the adoption of Medicare TC certification requirements in 2007. Concerns have concentrated primarily on the "disconnect" between CMS outcomes requirements for TCs and the conditions of certification of OPOs and on the impact of both OPTN and Medicare outcomes requirements on TC patient selection and organ acceptance practices. There is considerable evidence that these *outcomes requirements incentivize risk averse recipient selection and organ acceptance*--evidence that was sufficient to instigate Medicare's elimination of one-year patient and graft outcomes requirements as a condition of Medicare recertification in 2019. However, the OPTN retains the use of one-year outcomes requirements as a "trigger" for MPSC performance reviews, utilizing a methodology that, along with other triggers for review, results in MPSC review of an estimated fifty-four TCs each year. In addition, the use of a five- star rating system designed by the SRTR under contract with the Health Resources and Services Administration (HRSA) –a methodology that relies exclusively on one- year patient and graft outcomes-- has proven controversial and has incentivized TCs to avoid transplanting high risk recipients or accept high risk organs.

These *performance metrics have negative unintended consequences for patients* because they discourage aggressive acceptance of high-risk organs, causing more organs to be discarded and fewer patients to be transplanted. The current system has a disproportionately negative impact on the most vulnerable patients, those with lower socioeconomic status who often lack robust social support and tend to be referred later. Potential candidates with multiple medical comorbidities are more likely to have poor outcomes, and so do not get listed or are less likely to receive a transplant. Thus, the current system indirectly decreases transplants and at the same time decreases access to transplantation for many of the most vulnerable patients.

The high likelihood of unintended negative consequences of instituting additional metrics requires that their development be judicious. While the OPTN's use of outcomes measures as a trigger for MPSC review may have appeared benign for transplant recipients when instituted, the adoption of that same metric by CMS as a condition of certification resulted in a significant disincentive for TCs to accept organs at risk of discard or to transplant high risk recipients, thereby inadvertently decreasing patient access. *The "Centers of Excellence" designation by private payers is another unforeseen consequence of OPTN metrics, which forces centers to adopt markedly risk-averse behavior to maintain their participating provider status but harming patients by reducing access to transplantation overall*. The use of transplant rate as a metric by private payers and as a publicly reportable metric on Provider Specific Reports (PSRs) incentivizes TCs to be conservative in accepting patients for inclusion on their waitlists—an incentive that is clearly incongruent with CMS' focus on encouraging referral and transplant listing. In light of the complexity of transplantation at both the clinical and systems levels, it is critical to be cognizant of potential unanticipated consequences which may adversely impact patients.

The *distinction between system metrics and individual provider metrics is important*. Many advocate that there is a pressing need for increased collaboration among the various individuals and entities involved in the transplantation process, including OPOs, TCs, nephrologists, family physicians, transplant surgeons and physicians, dialysis facilities, the patient community, public health authorities and others. ASTS agrees and, in fact, proposed that the CMS Innovation Center institute a demonstration program focused on systems performance. *However, at this time, we believe that the change most capable of increasing the numbers of patients transplanted is removal of the disincentive for TCs to accept high risk organs or to transplant high risk recipients*. Therefore, this document addresses TC metrics, leaving the topic of systems metrics for future consideration.

ASTS believes that the difficulty in reaching consensus on metrics results in large measure from a lack of clarity regarding who is utilizing the metrics and for what purpose. Metrics will have different utility, and be viewed very differently, by potential recipients, payers, transplant centers and regulators. Publicly reported metrics should be distinguished from those used internally for quality improvement, as they are intended for different audiences and used for different purposes. It is critical to identify the intended purpose and impact of a proposed metric prior to its implementation. This document places metrics in four categories by their intended audience and their specific objectives:

- Metrics used for TC internal quality improvement;
- Publicly disclosed metrics;
- Metrics used to trigger OPTN/MPSC performance review of TCs;
- Metrics used in research to advance the field of transplantation.

I. Metrics Used for Internal Quality Improvement

Objective: ASTS believes that, within the constraints and requirements imposed by regulatory mandates, each TC should retain the flexibility to determine its own metrics for the purposes of quality improvement so that metrics used to improve performance are tailored to meet each institution's particular challenges.

TCs utilize a broad array of metrics to improve the care provided to patients via comprehensive Quality Assurance and Performance Improvement (QAPI) programs. ASTS believes that a Program's QAPI program is the primary tool to be used for performance improvement, and the importance of choosing the right process and outcomes metrics is critical.

CMS has published a detailed guide for surveyors detailing QAPI requirements for TCs, which clearly require that: "The transplant program must have objective measures for transplant processes/activities and outcomes for each phase of transplantation (pre-transplant, transplant and post-transplant) relating to transplant recipients and also for living donors."[1]

[1] https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf

The CMS guide offers many ways a TC may meet Medicare requirements for objective measures. TCs are encouraged to pick metrics they deem most relevant as they design and implement their QAPI programs. This allows each TC to focus its effort on metrics most likely to positively impact its patients.

ASTS believes that QAPI programs are most useful if they are individualized to address each TC's unique circumstances and if they remain sufficiently flexible to address emerging challenges. ASTS opposes the imposition of a uniform set of metrics for use by TCs in their internal quality improvement processes, instead encouraging the use of the metrics a TC's quality assurance committee and leadership believe will result in the greatest improvements in patient care.

II. Publicly Disclosed Metrics

Objective: ASTS believes that the primary objective of publicly reported metrics should be to comply with regulatory transparency requirements with respect to TC performance; to provide potential candidates with information they may find helpful in choosing transplantation as a treatment option; to provide the data necessary for them to compare transplant centers; and to provide this information in a straightforward and understandable format.

A. Metrics Required to be Publicly Reported under the Final Rule.

ASTS believes that the first priority with respect to publicly disclosable data is to comply with regulatory transparency requirements with respect to the scope and format of data to be made available. The Final Rule *(*at 42 CFR §121.11(b)(iv)) requires free internet dissemination of program specific information on:

- Risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant;
- Risk-adjusted graft and patient survival following the transplant; and
- Risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe.

This provision of the Final Rule also requires that the information provided be: "presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently."

Section 121.11(b)(iv)) of the Final Rule specifically requires that data be updated every six months and appears to interpret this requirement to mean that the data shall "be presented no more than six months later than the period to which they apply."

We believe that compliance with these requirements should be determined based on the "Program Summaries" available on the SRTR website, which are considerably more user-friendly than the full PSRs. The Program Summaries include:

- Waitlist mortality for each Program and nationally, expressed as "people [who] die per 100 years of waiting" for an eighteen-month period ending six months prior to the report

- A "Time to Transplant" Timeline that allows the viewer to calculate the percentage of patients receiving a transplant at the Program within various timeframes. However, the timeline tool is based on data for a period ending three and a half years prior to the report, and the SRTR website indicates that "these estimates are based on patients on the program's waiting list in the past and do not necessarily reflect how long a patient added to the list today will wait."

- The "Estimated Percentage alive with a functioning transplant at 1 year" for each Program, with data presented separately for living and deceased donors.

The Program Summaries appear compliant with regulatory transparency requirements in most respects; however, they do not appear to include "risk adjusted survival following listing."

ASTS believes that the publicly disclosed metrics required by the Final Rule could be modified to increase utility for potential recipients. We do not believe that the PSRs provide those data necessary for the typical potential recipient to "understand, interpret, and use the information accurately and efficiently." For example, the waitlist metric currently reported is based on "the number of deaths per 100 years of waiting time;" a concept that provides potential recipients little insight about their likely waiting time, while the more comprehensible waitlist timeline tool provided in the PSR Program Summary is based on data that is acknowledged to be out of date. ASTS recommends including organizations representing patient groups in discussions focused on ensuring that publicly disclosed data required by the Final Rule are presented in a manner that is concise and understandable for patients.

B. Comparative Public Metrics

The Final Rule does not require that PSRs include comparative TC ratings or any other comparative scorecard. The Final Rule (at 42 CFR §121.11(c)) authorizes but does not require the Secretary to disclose " comparative …patient outcomes at each transplant program." This information may be disclosed only if the Secretary "determines that the public interest will be served by such release."

We should consider how useful comparative data may actually be to potential recipients. Our most vulnerable patient populations lack the resources to travel to multiple TCs and lack the ability to "comparison shop" multiple TCs. For historically underserved poor and rural populations, the nearest transplant center is often the only one they can reach. Moreover, while Medicare fee-for-service beneficiaries may choose any Program in the country, it is anticipated that an increasing proportion of ESRD-eligible beneficiaries will enroll in Medicare Advantage plans in coming years,

and MA Plans typically restrict choice to those TCs in their network. For privately insured patients, TC choice is often determined based on payer networks. These geographic and insurance-related factors mitigate against the potential utility of comparative TC rankings for prospective patients.

Nonetheless, each PSR Program Summary currently includes comparative star (*) ratings for two metrics:

- Getting a Deceased Donor Transplant Faster; and
- Survival Following Transplant

The PSR Program Summaries specifically indicate that "Getting a Deceased Donor Transplant Faster" is the more important metric for kidney transplants. Living donor kidney transplantation results in superior outcomes for transplant recipients, as well as a favorable cost-benefit analysis, yet is strongly disincentivized by this system of rankings. There is considerable evidence that public dissemination of "Survival Following Transplant" ratings, which is a comparative rating of one-year graft and patient survival, is counterproductive, encouraging risk averse recipient selection and increasing wastage of potential useable organs. ASTS recommends elimination of the "Survival Following Transplant" star ratings as soon as practicable.

While ASTS believes that comparative ratings focused on how long a newly listed potential recipient is likely to spend on the waitlist are potentially useful to patients, it is doubtful that the current star rating system, which is based on a comparison of the programs' transplant rates (deaths per 100 years of waiting) are meaningful to patients. Patients may be more interested in clearer, quantified data (e.g., average waiting time at TC A vs. TC B). It is worth learning from patient advocacy groups whether, and how, data on time to transplant should be presented.

C. Possible Additional Public Metrics for Future Consideration

None of the current public metrics addresses a potential recipient's likelihood of making it onto a TC's waiting list, and the problem is exacerbated because "transplant rate" - which is a publicly reportable measure - disincentivizes longer waitlists. The problem may be more difficult to resolve than it first appears. The proportion of potential transplant recipients referred for evaluation and who are ultimately listed might appear to be an appropriate measure; however, such a measure may be skewed by wide variation on area nephrologists' referral practices, over which TCs have little control. A metric that measures the proportion of potential recipients who are evaluated and who are ultimately listed has the potential to disincentivize TCs from conducting full evaluations and to incentivize them to institute various pre-screening methods.

ASTS advocates reporting TC outcomes against the outcomes of the primary treatment alternative(s) for that particular end stage organ failure. We suggest displaying a kidney TC's risk adjusted outcomes against maintenance dialysis outcomes. Such a measure may help inform patient choice and encourage patients to seek transplantation and living donation.

III. Metrics Used to Trigger OPTN/MPSC Performance Reviews

Objective: The OPTN's initiative to evaluate TC metrics and monitoring approaches is intended to further the goal of increasing the number of transplants.[2] ASTS believes that OPTN/MPSC processes should further this goal by modifying the current outcomes-based methodology for triggering MPSC performance review and substituting a confidential peer review process designed to encourage TCs to increase the number of transplants performed without falling below established professionally acceptable outcomes parameters.

The bar for acceptable outcomes under the current system used to "flag" TCs for MPSC review has moved higher and higher. At this stage, the lowest performing centers may include those with one-year survival rates in excess of 95%. This use of these outcome measures to trigger MPSC performance review based on one-year patient and graft survival adversely impacts TC willingness to accept organs at risk of discard and to transplant higher risk recipients who still have a survival benefit from getting a transplant. The continued use of this methodology to identify TCs for MPSC performance review is incompatible with the objective of increasing the number of transplants performed. ASTS believes that it is crucial to eliminate use of this outcomes-based "flag" for triggering TC performance review in order to improve patient access to transplantation.

We support substituting a confidential peer review process designed to encourage TCs to increase the number of transplants performed without falling below established outcomes parameters. One option is to require centers to achieve an accepted minimum fixed survival floor, similar to a pass/fail grading system. Under this approach, a professionally acceptable outcomes standard would be established for each organ type (e.g., any renal transplant program with one- year graft/recipient survival of **x**% or greater will be deemed to be in compliance with OPTN outcomes requirements.) The fixed survival floor could step incrementally up or down based on the small number of variables for which there is robust and reliable data. This risk adjustment system, unlike the current system, would not grade TCs against one another on a curve and would incentivize centers to increase transplants performed.

The minimum performance standard should anticipate that outcomes might be impacted by aggressive efforts to increase transplant numbers and by innovation, especially as the science of transplantation and organ donation continue to evolve. Establishing a reasonable standard and eliminating the current trigger for MPSC performance review is indispensable in any effort to reduce risk aversion and increase access to transplantation.

Any new performance improvement process should be confidential, as are other peer review processes. ASTS congratulates the MPSC for the effort it has expended in changing its approach from "disciplining" to "engaging" members. The MPSC move towards promulgating process improvement through engagement, collaboration and education is laudable. They should continue

[2]https://optn.transplant.hrsa.gov/governance/strategic-plan/goal-1/

emphasize assisting underperforming TCs in identifying barriers to quality promoting best practices designed to overcome these barriers.

Any new metrics designed to encourage transplantation should be developed with the following principles in mind:

- Metrics should be based on measures that are directly under the control of the Program.
- Metrics should be easily understandable. The power of a metric to change behavior is diminished in direct proportion to its complexity. A fixed floor for one-year patient and graft survival is easily understood, would promote access transplantation and would foster innovation.
- Metrics should not conflict or overlap.
- TC assessment should incorporate changes in performance over time.

IV. Metrics for use in research

Objective: ASTS believes that the development of metrics focused on the long-term effects of transplantation should be developed to facilitate research in the field but should not be used as performance outcome triggers.

More data are needed about the long-term outcomes and quality of life of transplant recipients and living donors. However, it is not clear how those data can appropriately be used as metrics attributed to individual TCs or used in TC performance evaluation. ASTS believes that the use of quality of life and long-term outcomes metrics have the potential to contribute significantly to the field, but should not be used as performance review triggers at this time.

V. Conclusion

ASTS strongly believes that revision of the metrics used to evaluate TCs has the potential to drive change. However, the subject is complex, and requires input from the entire transplant community. It is critical that any new metrics be developed with the input of associations representing transplant surgeons, transplant physicians, organ procurement organizations, patient organizations and other stakeholders. While metrics used to trigger TC review by the MPSC will be implemented by the OPTN, and while public metrics will be calculated by the SRTR, organizations participating in the development of these metrics should not be limited to the OPTN and SRTR. Without meaningful participation of the entire transplant community new metrics are unlikely to be fully accepted, and critical strategic goals for increasing patient access to transplant listing and increasing the number of patients transplanted are unlikely to be achieved. ASTS looks forward to working with the transplant community to advance the quality of, and access to, transplantation to improve the way metrics are used and monitored.