NATIONAL KIDNEY
FOUNDATION®

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Richard Formica, MD
Yale Physicians Building
800 Howard Avenue, Ste 4th Floor
New Have, CT 06519

Dear Dr. Formica,

The National Kidney Foundation wishes to thank you and the Membership Professional Standards Committee (MPSC) of the Organ Procurement and Transplant Network (OPTN) for your presentation, "Improving transplant program metrics." Patients and patient advocates provide us with important information about the value of transplantation as a treatment modality, as well as the process of receiving a transplant. It is a longstanding priority of the National Kidney Foundation (NKF) to use this input to encourage the development and implementation of patient-centered measures of transplant center performance. These data are vital to patients and their families when choosing a transplant program.

In an early slide, a good metric was described as something that is important, reliably measured, has reliable data, can be impacted, and that the monitored entity accepts as important. We would add that a good metric must also be patient centered. As the transplant metrics effort continues both within and outside of the relatively narrow mandate of the MPSC, the Health Resources and Services Administration (HRSA), United Network for Organ Sharing (UNOS) and the Scientific Registry of Transplant Recipients (SRTR) should account for, before all other considerations, what is important to patients, despite the challenges of data collection and measurement. NKF agrees that the metrics used for transplant program monitoring must evolve with the changing regulatory and legislative landscape, for example recent allocation changes that are challenging centers in the delivery of high-quality care. We strongly encourage the development of and adoption by the MPSC of patient-centered measures as the transplant performance monitoring environment matures.

NKF appreciates the MPSC's efforts to make certain that transplant centers and OPOs are delivering high quality and equitable transplant care to the greatest number of patients. In general, we support changes to the current system by which transplant centers are evaluated to increase the focus on pretransplant metrics and decrease perceived disincentives to transplantation with less than perfect organs. This iteration in MPSC reviews reflects the community's desire to encourage the use of all viable organs and seeks to prioritize what patients most value, the opportunity to receive a transplant. Though we understand that the purpose of the new MPSC metrics is not to rank programs, the new metrics must be transparent to patients in order to allow them to access the data that they need to make informed decisions about transplant programs.

Specific comments on the proposed metrics follow. We acknowledge that some metrics may make more sense for one organ group than others. We encourage the MPSC not to choose single measures for consistency over the best measure of center performance for that organ program. Finally, we note the value of aligning the MPSC's transplant metrics efforts with those of CMS to ensure, to the extent possible, alignment across the incentives to which transplant centers respond. NKF looks forward to partnering with the MPSC, as well as other UNOS committees, the SRTR and HRSA to ensure that transplant performance measurement has the needs and preferences of patients at its center.

Proposed Measures

Waitlist Mortality Ratio

NKF is concerned about the way the benefits and harms of waitlist mortality were weighed in making the decision to include a measure of waitlist mortality for kidney transplant candidates. We agree that monitoring waitlist survival may result in unintended consequences including risk-aversion leading to denial of access to transplantation for patients perceived at higher risk of death on the waitlist. Recent evidence of increased waitlist removals, increased survival after removal and decreasing mortality on the waitlist are all evidence of the existing selectivity that already exists among transplant centers with respect to which patients they are willing to list. A waitlist mortality measure can also be gamed at the patient's expense. Some centers may adopt an approach of delaying listing, especially as waitlist times are extended. For many patients, this is emotionally devastating and can lead to decreased interest in making healthy choices on dialysis to achieve a transplant,

Access to the waitlist is important to patients because it reflects that transplant is a possibility, if not a guarantee. A population-based metric of access would be more informative than waitlist mortality. A recent analysis by Schold et al. found that access to the kidney transplant waitlist has not improved in the more than two decades since 1997 and has actually fallen among structurally disadvantaged populations.[1] We are extremely concerned by the potential for a waitlist mortality measure to exacerbate disparities in access to the waitlist. We also disagree that waitlist survival is a proxy for "the overall patient experience throughout the transplant process." While transplant centers are not the sole provider of direct patient care for waitlisted patients, transplant centers are responsible for communicating with patients, ensuring readiness for transplant, and providing empowering education about living donation. For patients, 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. These important center performance measures could be captured with process metrics (e.g., % of patients currently inactive on the waiting list or proportion of patients listed preemptively)

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[1] DOI: https://doi.org/10.1681/ASN.2020060888

NKF recommends removing the proposed waitlist mortality ratio measure in its current form. While we acknowledge that waitlist mortality is perceived relevant information for patients as they make decisions about where to receive care, the complexity of this measure, its association with factors outside the transplant center's control including social determinants of health, and the desire to increase access to the list exceed the value of the waitlist mortality as currently being considered as a regulatory metric. Along with other data that provide essential context, waitlist mortality should, however, be collected and reported in a patient-friendly format. We would emphasize again that waitlist mortality should not be used for regulatory purposes. If a waitlist mortality measure is considered essential by the MPSC, we propose that mortality is measured only for patients who have already received an organ offer. This would adjust for the highly variable waiting times across different regions of the country and also mitigate the unintended incentive to delay listing until a patient has accrued adequate waiting time to get an offer quickly.

Finally, flagging programs for waitlist mortality is misaligned with other transplant policy goals including reducing discard and increasing transplant referral. CMS has demanded that dialysis facilities and nephrologists refer centers and measures the proportion of patients who are placed on the waitlist. These are endeavors that NKF supports and are diametrically opposed to a measure that encourages centers to selectively list only the best candidates. Kidney care is already heavily siloed. All stakeholders (nephrologists, dialysis facilities, and transplant centers) must have aligned incentives in order for policies that aim to increase access to transplantation to be effective.

Offer/Acceptance Ratio

NKF strongly supports inclusion of a transplant center organ offer/acceptance rate measure. We believe this measure, if properly constructed, is fundamental to improving the current system. A key premise underlying an organ offer/acceptance rate measure is that kidneys that are currently discarded may have clinical value to patients when compared to dialysis or further time on the waitlist. NKF is a proponent of shared decision-making between patients and transplant centers. Patients' willingness to accept less than perfect organs may change numerous times during a patient's transplant journey. An organ offer/acceptance rate measure will further incentivize transplant programs to have regular conversations about patients' preferences. For example, ensuring that centers are reviewing and confirming each patient's signed consent form on organ offer preferences during reevaluation as age, circumstance, and preferences shift.

The organ offer/acceptance rate measure must be risk-adjusted for cold ischemia time and patient demographics. Cold ischemia times are currently unknowable but could be obtained for the purposes of risk-adjusting the measure. This is essential to prevent transplant centers from being held accountable for accepting organs with unacceptably high cold ischemia times, especially in light of broader sharing. While an organ offer-acceptance rate measure will encourage the appropriate use of UNOS filters by centers, increase the efficiency of the system and reduce organ discard from poor logistical coordination, the measure may be of limited value to patients who are trying to select centers with the highest probability of transplant after waitisting. We recommend that the organ offer/acceptance rate be provided both with and without the exclusion of the bypassed offers.

90-Day Graft Survival

Some patients raised concerns that 90-day graft survival is not a patient-centered measure because patients assume that survival of their transplant for 90 days is a given. We believe, however, that 90-day graft survival is an important measure for capturing safety concerns resulting from poor organ selection and patient management. Accordingly, NKF supports this measure.

Conditional One-Year Graft Survival

For immediate purposes, NKF supports conditional one-year graft survival. We understand that graft survival is a component of performance and relevant to OPTN's mandate to "monitor and review OPTN member performance, including threats to patient health." As metric development proceeds, however we encourage the MPSC and SRTR to look beyond one-year graft survival in two seemingly contradictory directions. Though transplant centers are familiar with one-year graft survival, it is well characterized that the focus on relatively short-term survival of the patient and graft has contributed to a culture of risk-aversion at transplant centers. We are also concerned that one-year graft survival may be misaligned with efforts to list and transplant more patients and to accept and transplant more less-than-perfect kidneys. Up to a point, transplant centers should not be penalized for giving patients the chance to receive a transplant. We support the maintenance of exclusion of particular high-risk groups (e.g., EPTS>85 transplanted with KDPI>85 organs) from this metric. This is consistent with the European "old to old" transplant program that encourages organ utilization. Patients opt into this system, so it is patient centric.

Conversely, most patients want and expect their transplants to last longer than one year. UNOS should track and SRTR should report 5-year outcomes compared with anticipated survival if they remained on dialysis. This transplant benefit calculation is consistent with patient expectations. Any outcome measures should be acuity-adjusted so as not to disincentivize transplantation of higher-risk patients and should be measured relative to medical management. Ultimately, outcome measurement is challenged by the fact that patients' desired outcomes must be placed into the context of the patient's life and thus are not the same patient to patient. It is our hope that the MPSC can strike the right balance between ensuring patient safety and giving transplant centers the flexibility to make the acceptance decision that align with each patient's values and preferences.

Aspirational/Experimental Metrics

Patients and living donors care very deeply not just about the outcome of transplantation, but also the opportunity to enter into the process of receiving a transplant and the efficiency and effectiveness of the process itself. The collection and reporting of data can be a preliminary step in the development of new metrics. Accordingly, we strongly support HRSA's collection of data on the early steps to transplant, prior to waitlisting at which point OPTN's oversight of the process begins. We ask HRSA to ensure that these data (e.g., evaluation rate as a % of all referrals, time to listing from referral and proportion of referred patients that are listed withing a predefined time interval e.g., 1 year) are collected and reported. We would also note the value of collaborating with the ESRD Networks and USRDS to align data collection and reporting efforts. The pre-waitlisting steps in the process, such as transplant referrals, the time-to-evaluation for transplant candidates and donors, the length of the evaluation, and the efficiency of listing can and should inform the evaluation of transplant center performance.

Finally, we recommend that the MPSC's performance monitoring effort align with SRTR's "Task Five." Task Five should develop patient-reported measures of the transplant process, a measure of shared decision-making regarding acceptance, and quality of life metric to supplement the current and proposed outcome measures. We would greatly appreciate the opportunity to participate in the process of conceptualizing new measures that are patient-centered and aligned with broader kidney care policies We do appreciate that measure development is limited by the lack of reliable data that exist and that are under the purview of the OPTN. NKF will be advocating for enhanced data collection across all elements of the transplant process that we expect will be able to inform the development of future performance metrics.

NKF appreciates the opportunity to hear from the MPSC directly regarding its transplant performance measure proposal. We hope the feedback contained herein will be useful in continuing to refine the proposal and in shaping the transplant metrics workstream across HRSA, SRTR, and UNOS. We look forward to partnering with each of these organizations to progress patient-centered metrics development. Please contact Miriam Godwin (miriam.godwin@kidney.org) to discuss further.

Sincerely,

Kevin Longino	Paul Palevsky, MD
CEO and transplant patient	President