Do Federal Regulations Have an Impact on Kidney Transplant Outcomes?

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Transplantation is one of the most highly regulated fields in health care. An important component of transplant oversight is the performance assessment of transplant centers as measured by 1-year patient and graft survival outcomes. The use of the Organ Procurement and Transplantation Network and Scientific Registry of Transplant Recipients flagging mechanism for quality improvement as criteria for Center for Medicare and Medicaid Services certification has resulted in greater importance in transplant program operations. Although supporters of this program of encouraging Quality Assurance and Performance Improvement point to improved survival outcomes for more than the decade, others assert that the oversight is unnecessarily punitive, results in tremendous resource utilization, and discourages innovation. Data exist to support an inhibitory effect on national transplant volume. Although survival outcomes are risk adjusted, limitations on national data collection prevent several important risks from being incorporated into the models. This has led to the consensus that many transplant centers have become increasingly risk averse in this environment, which may indirectly reduce access to transplant for candidates who could still benefit from transplantation. Recently enacted modifications to performance evaluation by Center for Medicare and Medicaid Services and the Organ Procurement and Transplantation Network appear to acknowledge these concerns and have the potential to recalibrate transplant center focus away from first-year outcomes and more toward expanding transplant volume, innovation, and overall improvements in care.

Key Words: Kidney transplant, CMS, OPTN, SRTR, Regulation

Transplantation, in part by its very nature, has always been a highly regulated field. The scarcity of deceased donor organs has long dictated that they be distributed in an organized fashion. The National Organ Transplantation Act of 1984 directed transplant centers on the use of organs in a variety of ways to ensure best use of organs and fairness to those awaiting transplantation. The Organ Procurement and Transplantation Network (OPTN), with United Network of Organ Sharing as its long-time contractor, has the authority to exert oversight of the operations of both transplant centers and organ procurement organizations, and in turn is supervised by the Division of Transplantation (DOT), a branch of the Health Resources and Service Administrations. The scope of OPTN oversight extends from policy development to organ allocation and distribution, to quality assurance.

OUTCOME REGULATION

The OPTN has long monitored the outcomes of solid organ transplants and the transplant centers that perform them. The findings are transmitted via the Program-Specific Reports (PSRs), and a comprehensive report or analysis of transplant center activity and outcomes is produced by the Scientific Registry of Transplant Recipients (SRTR), which provides analytic support to the OPTN and DOT. Central to the PSRs—from the oversight perspective—is the reporting of graft and patient survival outcomes. In kidney transplantation, transplant center patient and graft survival rates at 1 month, 1 year, and 3 years are reported for the preceding 30-month cohort for which adequate follow-up is available. The overall experience is further subdivided by living or deceased donor type, as well as adult or pediatric recipient type.

The observed survival rates and death counts or graft failures are compared with an expected measure that is derived from a comprehensive survival model based on national donor, recipient, and transplant data and is adjusted for the composite risk. Thus, a center can assess its experience based on what would be expected if the center were performing on par with the national average. The statistical models can also identify if the outcomes of a center are significantly better or worse than expected. For many years, these models were available to centers for the purposes of quality improvement, with feedback given to transplant centers by the Membership and Professional Standard Committee (MPSC) of the OPTN. This process served as a peer review mechanism to engage transplant centers in quality improvement. In theory, the MPSC had the authority to declare a center a member not in good standing, on the basis of outcomes. In practice, such a declaration rarely occurs.

In 2007, the Center for Medicare and Medicaid Services (CMS) established conditions of participation (COPs) for transplant centers.[1] These conditions were comprehensive and covered a broad spectrum of transplant program activities. Most importantly, adequate outcomes of the performance based on SRTR PSR methodology became a mandatory condition for CMS certification, which is essential for the operation of a kidney transplant program. This new requirement had a profound effect on transplant centers for a variety of reasons: (1) a large number of transplant programs were affected—as many as 10% per reporting period, with most programs affected at one time or another; (2) the potential for termination of CMS coverage for kidney transplantation, which is formally threatened

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for identified programs, is viewed as an existential threat; (3) although there was a recourse for transplant programs under the threat of termination, to receive certification by showing commitment to Quality Assurance and Performance Improvement (QAPI) and demonstrating improved short-term outcomes, the likelihood of approval on this basis was initially unknown; (4) programs that entered into System Improvement Agreements (SIAs) with CMS to avoid termination reportedly had significant disruptions in program operations and severe reductions in transplant volume; and (5) inherent to the 30-month cohort length and reporting a cycle of only 6 months was the fact that short-term improvement in the outcome could not be immediately apparent in PSRs, further dampening confidence that these improvements would be appropriately recognized. Although adjunct tools, such as CUSUMs,[2] were developed to help assess changes closer to real time, such data did not negate getting flagged.

These concerns had the effect of making transplant centers as focused on the status of their center outcomes as serving the best direct interests of their patients. As an initial reaction to the goal of avoiding substandard survival outcomes, many centers reportedly became more risk averse, and there is ample evidence in the literature that this is at least partially the case. A leveling off of national kidney transplant volumes[3] was interpreted by many to coincide with the introduction of the COPs, whereas others argued that the COPs promoted the establishment of the needed QAPI infrastructure that improved outcomes without reducing the number of transplants performed.

CLINICAL SUMMARY

- Regulatory action likely has improved outcomes.
- Some aspects of the risk modeling, particularly in regard to socioeconomic factors, are not included, which may result in access disparities.
- New regulatory methodology may decrease the administrative burden of the review process.

Transplant survival outcomes have improved since the establishment of COPs by CMS. CMS cites this as strong evidence of the positive impact of the program and refers to transplantation as a role model for quality improvement in health care. Critics view this improvement as a direct result of risk-averse behavior by transplant centers in response to the COPs. Of note, the survival performance threshold far exceeds the survival that ensures a benefit to transplantation. However, there is likely a balance between comprehensive risk adjustment and encouraging futile transplants (Fig 1).[4] Thus, if indeed, outcomes have been improved by avoiding higher risk candidates, these are likely to be candidates whose survival nonetheless would have been improved by transplantation. The transplant community expressed discontent over what was perceived to be a highly restrictive and punitive mechanism.[4,5] Furthermore, although a review by CMS or the OPTN can result in program improvements, the process is expensive and resource intensive. Recent actions by the OPTN and CMS appear to be directed at these concerns and will hopefully have the effect of reducing any risk-adverse behavior that may exist related to oversight.

CENTER REVIEW PROCESS

Centers that are flagged for outcomes, whether by OPTN or CMS, are expected to intensify their QAPI processes to address substandard outcomes. These include root cause analyses of events, analyses of patient-level data to identify types of patients where outcomes are worse than expected, and corresponding corrective actions. Although transplant center QAPI is far more mature than when CMS first issued COPs in 2007, most centers need to accelerate their QAPI activities when faced with a regulatory review of outcomes. This generally results in an increase in resource utilization, which could come at the expense of patient care or innovative initiatives.

For centers that are cited for condition-level violations by CMS and are facing termination, the stresses are further amplified. These centers are generally expected to undergo a comprehensive peer review process, usually by a professional independent peer review team (IPRT), to maximize their QAPI efforts in advance to submission of a mitigating factors' letter or establishment of an SIA. Centers are expected to comply with the IPRT recommendations. Both the review and the associated corrective actions require further resource utilization.

Being under the threat of termination by CMS also threatens the stature of the transplant program internally and externally. Although in practice, transplant programs have rarely closed purely because of outcome issues, the lack of understanding of the flagging systems, its weaknesses, and the large percentage of centers that get flagged, can lead to exaggerated perceptions of programmatic struggles or failure. Programs are required to inform patients of substandard outcomes; when under an SIA, patients are directly given the option to transfer care to another center. This also impacts relationships with referring physician groups and threatens to disrupt referral streams. All these repercussions sap transplant staff morale.

In our experience, there is rarely a smoking gun or neat narrative to easily explain substandard outcomes. Quality improvement probably results from changes in a number of different arenas, including donor and recipient selection, post-transplant care, and data-directed protocol modifications. The lack of an easy single solution means that with so much at stake, many changes are often made at the same time, without the confidence that any one is the answer to improved survival. Thus, it is easy to understand why risk-averse behavior ensues that likely affects candidate evaluation, donor selection, ultimate acceptance for transplant, and willingness to try new treatments or protocols. Transplant programs that are flagged do fewer subsequent transplants and have higher rates of delisting. Those centers that do improve outcomes emerge with some degree of insight into how they