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Editorial

Are the Centers for Medicare & Medicaid Services metrics evaluating organ procurement organization performance too fragile?

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Quality metrics are ubiquitous in health care in the United States and entrenched in the field of transplantation, including mandatory public reporting of both organ procurement organization (OPO) and transplant center performance. There have been numerous iterations in scope and implications of quality reporting for transplant providers, including those by Centers for Medicare & Medicaid Services (CMS), the Organ Procurement and Transplantation Network, and the Scientific Registry of Transplant Recipients. Notably, after years of evaluating transplant center performance as part of their Conditions of Participation for transplant centers, CMS discontinued the use of 1-year posttransplant outcomes for assessment of transplant center performance in 2019. This change was the result of thoughtful evaluation and acknowledgment of significant unintended consequences associated with performance evaluations, including “decreased utilization of marginal organs” and “deselection of patients from the waitlist.”¹

More recently, CMS published a final rule updating the Conditions of Coverage to evaluate OPO performance supported by evidence of significant variation in processes of care leading to varying levels of donation and transplant rates between donor

service areas.² Although there is a perceived need to implement quality assurance to objectively evaluate OPO performance, measuring quality of care in the context of organ donation is complex. In the current study published in the *American Journal of Transplantation*, Miller et al³ evaluate quality tier reclassification of OPOs with and without inclusion of risk adjustment for race in the underlying statistical models. The primary finding was that 8 (14%) of 58 OPOs shifted quality ranking (tier) with the introduction of this single variable. The authors also highlight that this reclassification includes OPOs that otherwise have the worst ranking (tier 3) without adjustment for race despite better performance among non-White populations. The authors suggest that inclusion of race into the statistical models is more appropriate to measure performance given the potential nonbiological impact of race on donation and transplant processes and has the added ability to evaluate OPO performance based on racial subgroups.

The current findings follow a study with a similar design by Lopez et al⁴ which demonstrated that 19% to 31% of OPOs change performance tier rankings with adjustment for age (in the donation model) and donor residential area deprivation. There is

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also extensive evidence that nonbiological factors such as race and social determinants of health impact every step of the transplant process, including waitlisting, donation, and organ utilization. These data are particularly notable given that, as the CMS regulations are currently framed, OPOs in the bottom tier rankings will lose certification. As such, a change in tier ranking invokes profound consequences to the viability of OPOs in a context central to the transplantation process. The 2023 CMS performance report suggests that, currently 24 OPOs (42%) are in the lowest tier serving nearly 41% of the US population.

In statistical terms, these studies suggest that the CMS models are fragile. Here, the term fragile suggests that deviation from model assumptions (in this case, additional risk adjustment) leads to substantial changes in inferences (in this case, rating OPO performance). This fragility, in the context of highly consequential ramifications, may be concerning without clear evidence validating poor OPO performance beyond current models. The risk of CMS policy could be that multiple OPOs falling in a bottom tier, which would not have been identified with additional risk adjustment, would no longer be allowed to continue services. Conversely, some “poor performing” OPOs will not be identified as such and will be allowed to continue to provide services.

The use of race and other sociodemographic factors for risk adjustment in health care report cards has been a source of ongoing debate, but there also is significant precedence. In 2017, the National Quality Forum, an organization charged with vetting quality metrics for CMS, published a white paper on this particular topic.⁵ The primary conclusion of the report emphasized the value of integrating sociodemographic factors into risk adjustment models when a clear conceptual framework supports their influence on outcomes of interest. Furthermore, it emphasized the necessity of stratifying results based on these factors to illuminate potential disparities in care. It is notable that race and ethnicity have historically been and are currently used in risk adjustment models evaluating transplant center performance with the recognition that race is a social construct and not a biological variable.

Since the passage of the Conditions of Coverage, there is compelling evidence that OPOs have had the capacity to improve. The sharp rise in available donor organs in recent years has likely been motivated by CMS policy and suggests there has been an unmet opportunity to facilitate more transplantable organs to patients. The recent improvements may be regarded as a policy success, underscoring the potential impact of quality metrics. However, the next question is more difficult—which OPOs are performing at a level that warrants exclusion? It is important to note that based on a normative reference, the policy could lead to a revolving door (or a shrinking pool) of OPOs with additional performance cycles—and the attendant challenges of disruption to the donation/transplant process. Concerns about the inclusion of race in OPO models were largely centered on permitting inequities in donation to persist. However, as shown by Miller et al.,³ the absence of race in models has allowed some OPOs to continue to underperform among racial subgroups rather than illustrating disparate performance and developing targeted improvement.

With evidence that the current CMS model is fragile and more could be learned to promote improvement by

understanding differential success in subgroups of the population, should current CMS policies be reconsidered? In addition, with the clear desire to regulate OPO performance and evidence of critical data not integrated into quality metrics, there seems a clear need for broader, more systematic data collection supported by regulators to improve models and enhance the opportunity for quality improvement. Regulators owe it to patients to ensure that quality metrics reliably measure what they purport to and that adverse consequences are mitigated once they become apparent. Further consideration of other quantitative and qualitative measures for evaluating processes of care among OPOs is also warranted. Although no one would argue against setting appropriately high-performance thresholds or reducing unneeded variation, doing so with valid and methodologically robust measures that clearly identify improvement opportunities is essential to maximizing access to transplantation for our patients.

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