**Written Statement of the American Society of Transplant Surgeons**
To the National Academies of Sciences, Engineering, and Medicine
Committee on
A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution
July 15, 2021

Thank you for the opportunity to provide this written statement on behalf of the American Society of Transplantation (ASTS) to the National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution. ASTS is a medical specialty society representing approximately 1,900 professionals dedicated to excellence in transplantation surgery. Our mission is to advance the art and science of transplant surgery through patient care, research, education, and advocacy. We welcome NASEM's interest in this area.

We understand that the Committee is particularly focused on four specific areas of interest: equity, transparency, aligning incentives, and increasing rates of organ donation and acceptance. ASTS is extremely active in pursuing policies that improve access, identify and address disparities, and improve efficiency without reducing quality. Our fundamental objective is to align regulatory incentives to increase the number of clinically appropriate transplants while maintaining quality and to align stakeholder incentives to ensure increased access and optimal organ identification and utilization. Our activities are guided by our ASTS *Statement of Principles on Organ Donation and Transplantation* (*Statement of Principles*[1]), which specifically addresses the topics of concern to the Committee.

Equity

ASTS' *Statement of Principles* specifically addresses the need to identify and eliminate processes and practices that discriminate on the basis of race, gender, gender identification, religion, ethnic background, disability, or other factors. Last year, ASTS launched a national campaign, ***ASTS Boldly Against Racism*** (accessible HERE), to directly address racism and to promote permanent and positive change. Among other things, this initiative involves dedicating funding for ASTS members to promote the scholarship of identifying and addressing structural barriers, including systemic racism, that contribute to racial disparities in transplant access and outcome.

[1] https://asts.org/about-asts/position-statements

In line with this campaign, ASTS supports limiting the consideration of non-clinical factors in waitlist practices[2] and has taken a stance against discrimination against potential transplant candidates based on physical and mental disabilities.[3]

ASTS believes that the transplant community needs to take responsibility to undertake the substantial work that needs to be done to eliminate racial disparities in access to treatments for organ failure and to better understand and address racism as a fundamental driver of racial disparities in access to health care and transplant access. At the same time, it is important to acknowledge that policy changes are often required to make real progress to advance equity. For example, targeted initiatives[4] to change the national kidney allocation policy have resulted in comparable rates at which Black/African American, Hispanic, and White transplant patients who make it to the waiting list receive kidney transplants from deceased donors.[5] Additional targeted efforts, such as the removal of structural barriers to transplant referral and placement on the waiting list are needed to further reduce transplant disparities for vulnerable populations.

One of the most pressing changes that should be made with respect to the use of racially biased algorithms in transplantation relates to the use of a race correction in the Estimated glomerular filtration rate (eGFR) calculation, which is used to measure a patient's level of kidney function and determine the patient's stage of kidney disease. There is strong clinical evidence that the use of race correction in the eGFR calculation adversely impacts access to transplantation for Black patients with kidney disease.[6] The ASTS has together with other professional societies, including the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) have recommended "that race modifiers should not be included in kidney function estimating equations, and that a suitable approach be put in its place that is accurate, representative for all regardless of race, ethnicity, age, or sex; not differentially produce bias, inaccuracy, or inequalities; and be standardized across the United States."

More upstream, Black, Hispanic, and other medically underserved patients deserve timely access to high-quality primary healthcare, leading to prevention and prompt diagnosis of kidney disease, diabetes, fatty liver disease, hepatitis, heart failure, chronic lung disease and the appropriate early referral to

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[2]See ASTS comments submitted supporting the OPTN White Paper ***General Considerations in Assessment for Transplant Candidacy***

[3] *ASTS Statement Concerning Eligibility for Solid Organ Transplant Candidacy. Drafted by the ASTS Ethics Committee and approved by the ASTS Council February 12, 2021*.

[4] Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020 Aug 27;383(9):874-882. doi: 10.1056/NEJMms2004740. Epub 2020 Jun 17. PMID: 32853499.
Eneanya ND, Yang W, Reese PP. Reconsidering the Consequences of Using Race to Estimate Kidney Function. JAMA. 2019 Jul 9;322(2):113-114. doi: 10.1001/jama.2019.5774. PMID: 31169890.
Boulware LE, Purnell TS, Mohottige D. Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations. JAMA Netw Open. 2021 Jan 4;4(1):e2034630. doi: 10.1001/jamanetworkopen.2020.34630. PMID: 33443577.

[5] https://unos.org/news/odds-equal-of-kidney-transplant-for-minorities/

[6] Vyas DA, Eisenstein LG, Jones DS. Hidden in Plain Sight - Reconsidering the Use of Race Correction in Clinical Algorithms. N Engl J Med. 2020 Aug 27;383(9):874-882. doi: 10.1056/NEJMms2004740. Epub 2020 Jun 17. PMID: 32853499.
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specialized care and to transplant centers. As with all forms of healthcare disparities, addressing this issue effectively is complex, requiring changes at multiple levels of the healthcare system.

As a society of transplant professionals, we will continue to work closely with our medical and professional colleagues and their organizations, patient and community advocacy organizations (e.g., National Minority Organ Tissue Transplant Education Program, American Association of Kidney Patients), and our own society members who are experts in the scholarship of race and health equity to develop a multi-pronged strategy to advance the field.

Transparency

The ASTS strongly supports transparency. The ASTS also recognizes that more data is publicly available regarding virtually every aspect of transplantation than for any other field of medicine. We believe that the public interest in transparency is not necessarily served by more data: What is necessary is to determine the goals of the transplant system and then to access what data is useful to achieve these goals and to grant public access to this data and ensure public trust in the system that is crucial to maintain the altruistic system of donation supported by the public. For this reason, *ASTS Recommendations for Optimization of Transplant Center Assessment* calls for the meaningful involvement of patient advocacy organizations to identify what information is important to patients and to provide guidance regarding user-friendly formats for the presentation of this information.

We also believe that it is critical for information related to transplantation to be presented to the public in context. For example, any information provided to the public regarding kidney transplant outcomes should be presented along with the outcomes for alternative treatment modalities (e.g., dialysis). The ASTS *Recommendations for Optimization of Transplant Center Assessment* states that:

> *Publicly available data should include 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).*

Finally, care should be taken to ensure that sharing data about outcome and other efforts to increase transparency should focus on quality and transplant availability rather than comparative, competitive, or punitive assessments that decrease patient access, decrease the potential for innovation, or have other unanticipated consequences. For example, all peer review processes, including the peer review process conducted by the OPTN, should be conducted in a manner similar to other fields of medicine that is confidential and protected from public disclosure in order to advance the effectiveness of the quality review process. Likewise, the current five-star ratings of transplant centers based on one-year graft and patient survival are used by third party payers to trim their participating provider networks thereby reducing patient access, as well as dissuading transplant centers from utilizing less than perfect organs, discouraging centers from transplanting riskier recipients, and encouraging conservative waitlist practices. Finally, managing data and public reporting should be aligned to an iterative transplant system that constantly reviews and adjusts elements of reporting based on their impact on organ availability and patient outcome. This alignment should be hard wired into the system to ensure achievement of the most patient benefit.

Aligning Incentives

ASTS believes that the incentives of various providers and other organizations involved in the transplantation ecosystem are seriously misaligned and has dedicated years of advocacy to efforts to eliminate or mitigate conflicting incentives, with partial success. In particular, the most egregious misalignment of incentives arises as the result of the current outcomes metrics used to evaluate Transplant Center performance, which encourage transplant centers to be risk averse in organ acceptance and recipient selection. This directly conflicts with strong incentives created by the new OPO Conditions for Coverage (CfC) for OPOs to facilitate transplantation of all organs procured and is inconsistent with the need to increase access to transplantation more generally.

More specifically, while one year graft and patient survival metrics are no longer used as a condition of Medicare re-certification, outcomes metrics are used by the OPTN Membership and Professional Standards Committee (MPSC) to evaluate transplant center performance, a process that can result in significant operational disruption, enmesh the center in quasi-judicial OPTN sanctions processes, and divert time and attention from patient care. In addition, a drop in performance on the five-star outcomes rating system included on Provider Specific Reports can and does result in loss of patients, reputation, and private payer contracts. There is substantial evidence that the use of these types of metrics triggers risk averse behavior by transplant centers, reducing access.

The emphasis on outcomes measurement would make considerably more sense if, in fact, there were significant variations among Transplant Centers in one year graft or patient survival. Currently such variation is minimal: Today, one year patient and graft survival rates almost universally exceed ninety percent, and even transplant centers in the lowest quartile average one year patient and graft survival in the range of 93%. Close examination of the current system reveals that 63% of transplant centers with 100% risk adjusted one year patient and graft survival are designated as having only three (out of five) stars—that they are operating "as expected." With such a system in place, how likely are these centers to accept a greater number of organs at risk of discard (so-called "marginal" organs)?

ASTS has urged HRSA to modify the current performance measurement system to drop the five-star system for public rating of Transplant Centers; to require the OPTN to modify its current outcomes-based system for performance reviews; and to substitute a system that places the emphasis on access and equity. As stated in the *Statement of Principles:*

> *ASTS supports elimination of public display of transplant center ratings and certain performance assessment outcome metrics that compare transplant centers to one another. Such display disincentivizes the transplantation of usable organs at risk of discard and the transplantation of those candidates that are most vulnerable. Alternatively, we support performance metrics that motivate increasing the use of all transplantable organs and promote the transplantation of all patients who will benefit, including the most vulnerable candidates.*

There are numerous other misaligned incentives that make the system less efficient than it could—and should—be. For example:

- OPO CFCs encourage use of organs at risk of discard.

*BUT the current organ allocation methodology does not provide the flexibility for transplant programs to appropriately match organs at risk of discard with the patients for which these organs may be clinically appropriate.*

- CMMI demonstrations and CMS quality incentives for dialysis centers and nephrologists to get their patients waitlisted.

  *BUT "Time to Transplant" star ratings incentivize Transplant Centers to trim waitlists*.

- Organ Recovery Centers have the potential to moderate Organ Acquisition Cost (OAC) increases resulting from OPO CfCs.

  *BUT CMS cost accounting rules disincentivize Transplant Centers from using Organ Recovery Centers to recover organs.*

To help address these types of misalignment, ASTS submitted an application for a demonstration program to the CMS Innovation Center that would align incentives for all organizations involved in transplantation in the demonstration project's service area (including the dialysis facilities, transplant center(s), transplant professionals, OPOs, nephrologists, patient organizations and others), so that all participants have an incentive to increase the number of transplants performed over a historically determined baseline. Under the proposed model, regulatory disincentives to transplantation would be suspended and participants would share Medicare program savings resulting from transplantation (as compared with dialysis). In its nationwide demonstration program, CMMI took a different approach.

<u>Increasing Rates of Donation and Acceptance</u>

ASTS recognizes that organ acceptance practices vary among centers and for individual patients based on their risk. We believe that efforts to increase the number of organs at risk of discard that are accepted for transplantation should begin with the elimination of the disincentives to transplant created by our current system for measuring transplant center performance and should be augmented by focused educational efforts. ASTS *Statement of Principles* states:

> *ASTS supports efforts to encourage the acceptance of organs at risk of discard through educational efforts, the identification and adoption of best practices, and implementation of evidence-based guidelines.*

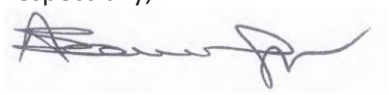
To facilitate this type of educational effort, CMS is launching the CMS Kidney Transplant Learning Collaborative, whose objective is to increase kidney transplant 15% over a five-year period. ASTS embraces this objective and is enthusiastic about participating.

However, ASTS does not believe that organ acceptance decisions should be subject to regulatory pressure or constraint. Our patients expect to receive organs that will benefit them beyond one year and provide them significant improvement in their quality of life. The *Statement of Principles* states:

> *Any decision to accept an organ for transplantation is highly complex, involving multiple clinical considerations, and should be made by transplant teams based on the best interests of the potential organ recipient without reference to regulatory pressure or constraint.*

So, a critical clinical decision should be free of regulatory interference. Neither incentives that encourage more conservative clinical decision making—such as the outcomes-based metrics currently in place—nor those that encourage more aggressive decision making—such as metrics that measure center performance based on the number of organs accepted for transplantation—has a legitimate place when it comes to evaluating what is in each individual patient's best interests.

Respectfully,



A. Osama Gaber, MD, FACS
President
American Society of Transplant Surgeons