

February 4, 2021

Lee A. Fleisher, MD
Chief Medical Officer and Director
Center for Clinical Standards & Quality (CCSQ)
U.S. Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Fleisher:

The American Society of Transplant Surgeons (ASTS) very much appreciates the time that you and your staff spent with us discussing the pressing need for increased coordination among the various CMS Centers and between the Center for Clinical Standards and Quality (CCSQ) and the Health Resources and Services Administration (HRSA) Healthcare Systems Bureau with respect to the regulation of transplantation. We request a joint meeting between CMS/CCSQ and HRSA/Health Services Bureau (Division of Transplantation) to address the most pressing issue, the conflict between incentives created by the recently finalized Organ Procurement Organization certification regulations and Transplant Center performance metrics currently used by HRSA contractors.

More generally, we strongly believe that increased coordination has the potential to substantially increase the availability of renal¹ and other transplantation in the United States, by reconciling the conflicting incentives of various components of the transplantation ecosystem. For example:

- CMS' new Organ Procurement Organization (OPO) certification requirements strongly encourage OPOs to increase the transplantation of all organs retrieved (including organs perceived as "marginal"); yet the Transplant Center (TC) outcomes metrics used by HRSA contractors (the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR)) to measure TC performance strongly incentivize TCs to refrain from accepting organs viewed as "marginal" and from transplanting less healthy patients.
- CMS' new OPO certification regulations encourage OPOs to acquire pancreata for islet transplantation and research; yet FDA regulation of allogenic islets has virtually stopped islet transplantation in the United States. For data, see Attachment A.

¹Transplantation can be life-saving. We are cognizant of the fact that renal transplantation almost always has better patient outcomes, compared to remaining on dialysis. Tonelli M, Weibe N, Knoll G, et al. Systematic review: kidney transplantation compared to dialysis in clinically relevant outcomes. *Am J Transplant.* 2011;11:2093-2109.

President

Marwan S. Abouljoud, MD, CPE, MMM
Henry Ford Transplant Institute

President-Elect

A. Osama Gaber, MD
Houston Methodist Hospital

Secretary

Ginny L. Bumgardner, MD, PhD
The Ohio State University

Treasurer

William C. Chapman, MD
Washington University

Immediate Past President

Lloyd E. Ratner, MD, MPH
Columbia University

Past President

Dixon B. Kaufman, MD, PhD
University of Wisconsin

Councilors-at-Large

Michael J. Englesbe, MD
Julie K. Heimbach, MD
Debra L. Sudan, MD
Matthew Cooper, MD
Ryutaro Hirose, MD
Kenneth Washburn, MD
Kenneth A. Andreoni, MD
Devin E. Eckhoff, MD
Irene K. Kim, MD
Ashley H. Seawright, DNP, ACNP-BC

Executive Director

Daniel D. Garrett, CAE
daniel.garrett@asts.org

National Office

1401 S. Clark St.
Suite 1120
Arlington, VA 22202
703-414-7870
asts@asts.org
ASTS.org

American Transplant Congress

June 5-9, 2021
Seattle, Washington

- CMS' new OPO certification regulations strongly encourage OPOs to increase transplantation; yet CMS Center for Medicare cost-reporting rules strongly disincentivize the establishment of Organ Recovery Centers, which have been shown to increase organ yield, while decreasing the costs associated with organ donation.²
- While the ESRD Quality Improvement Program and various demonstration programs initiated by the CMS Centers for Medicare and Medicaid Innovation (CMMI) include measures incentivizing dialysis facilities to get their patients waitlisted, the Transplant Rate "star ratings" included on TCs' public "Program Specific Reports" (PSRs) (made available under HRSA auspices through the SRTR) encourage TCs to be conservative in adding new patients to their waitlists and incentivize the removal of patients from inactive waitlist status.³

We believe that there is an immediate and pressing need for CCSQ and HRSA's Healthcare Systems Bureau/Division of Transplantation to work together to eliminate the first listed and most critical of these conflicting incentives. The rationale and supporting data for our request are set forth below.

The Need to Reconcile OPO Conditions for Coverage and OPTN/SRTR Outcomes Metrics

Available data establishes that OPO certification requirements recently adopted by CMS create extraordinarily strong incentives for OPOs to increase the transplantation rate of the organs they procure. Under the new regulations, by 2024, 23% of all OPOs will have to increase the number of organs transplanted by 20% or more, and 10 percent of OPOs will have to increase the number of organs transplanted by nearly 40%. See chart at Attachment B.

By contrast, a considerable body of literature establishes that TCs have an equally strong incentive to reject organs that are viewed as "marginal" and to avoid transplanting potential recipients who are viewed as riskier. This disincentive arises as a direct result of outcomes-based metrics that, while discarded by CMS as a condition of TC recertification, remain in effect to "flag" TCs for performance reviews conducted by the Membership and Professional Standards Committee (MPSC) of the OPTN and to determine the TC's "star ratings" for publication on public-facing websites. Both employ one-year patient and graft survival outcomes metrics that CMS repealed as a condition of recertification because it found that such metrics disincentivize transplantation.

To put this issue in context, it is critical to note that, based on 2016 data, receiving a transplant at a highly underperforming center still greatly improves survival when compared with remaining on the waiting list for end-stage renal disease patients.

²For data, see Doyle M, Subramanian V, Vachharajani N, Collins K, Wellen JR, Stahlschmidt E, Brockmeier D, Coleman J, Kappel D, Chapman WC. Organ Donor Recovery Performed at an Organ Procurement Organization-Based Facility Is an Effective Way to Minimize Organ Recovery Costs and Increase Organ Yield. *J Am Coll Surg*. 2016 Apr;222(4):591-600. doi: 10.1016/j.jamcollsurg.2015.12.032. Epub 2016 Feb 29. PMID: 26947113.

³See <https://xynmanagement.com/transplant-rate-new-metric-worry/>.

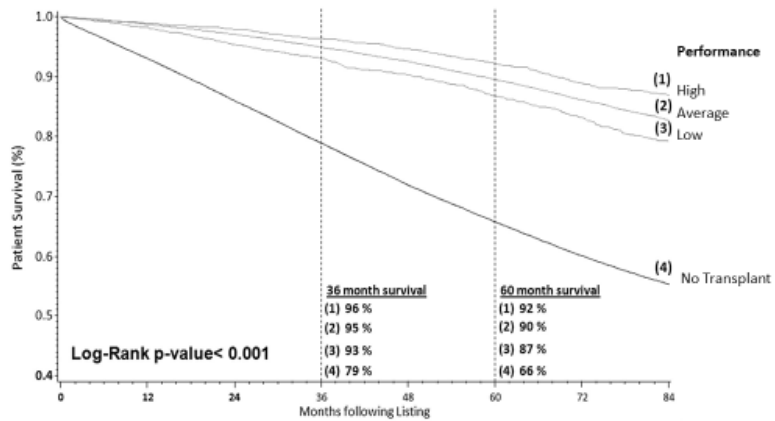
Context

Patient survival from time of listing for deceased donor kidney transplant:

1,2, and 3 - Transplant performed stratified by center performance

4 - Survival with No Transplant

A Kidney Transplant Always Yields Better Survival than No Transplant*



Jesse D. Schold et al. CJASN 2014;9:1773-1780

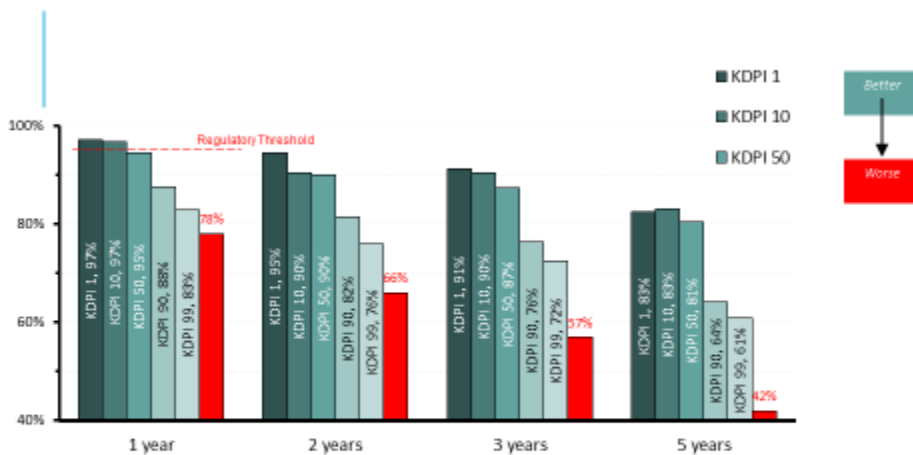
©2014 by American Society of Nephrology

* In properly selected patients



In addition, USRDS data shows the disincentive to use marginal (higher KDPI) kidneys, in an effort to maintain the mandated regulatory transplant success rates. The outcome rates for remaining on dialysis are contrasted as well. Even the most marginal kidneys have better outcomes than remaining on dialysis.

REGULATORY PRESSURE ON LESS THAN PERFECT KIDNEYS VS. DIALYSIS



Donor reference population: All deceased kidney donors recovered for transplant in 2016. Based on OPTN data including primary, adult, deceased donor, kidney alone transplants, as of April 20, 2018.

https://www.usrds.org/2017/view/v2_05.aspx

The data support the proposition that TC performance metrics that disincentivize transplantation are not in the best interests of patients.

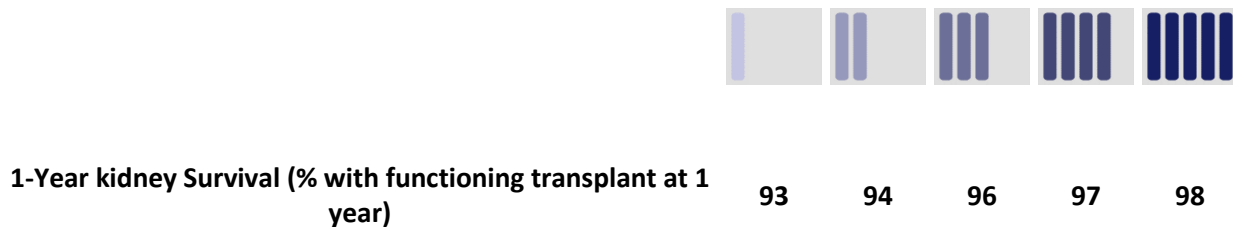
With these considerations in mind, ASTS has adopted a position statement calling for the elimination of outcomes-related star ratings and revision of the OPTN trigger for TC performance review that would essentially require a minimum level of outcomes performance, rather than evaluating TC performance on a comparative basis. Our position statement is set forth at Attachment C.

a. TC Star Ratings

In or around 2018, the SRTR (with the approval of HRSA) implemented a five-star rating system for TCs. The number of stars earned by each TC is displayed prominently on the TC’s PSR, which is made publicly available and is used by both patients to determine where to get waitlisted⁴ and by payers to determine assess and whether to include (or continue to include) a TC in its network.

The 5-tier system does not use a traditional test of statistical significance to demonstrate that a TC is doing better or worse than expected. Instead, the 5-tier system ranks all TCs in a single list, based on how they performed relative to expectation (taking into account risk adjustment), and uses defined cutoffs to separate TCs into five groups.⁵ Because of increasingly positive one-year outcomes for kidney transplantation overall, a TC’s star rating can fall significantly with only one or two adverse outcomes.

In fact, the most recent SRTR data indicates that the one-year outcomes for even “one star” TCs is 93%:



The five-star rating system for TC outcomes is so volatile that almost half of kidney programs have a change in ratings within six months and more than half shift by two stars within four years, making the star ratings unreliable for potential recipients seeking to determine where to be waitlisted.⁶ In addition, lower star ratings are not associated with eventual post-transplant outcomes in either kidney or heart transplantation.⁷ Yet, a survey of transplant programs established that over half of programs whose star

⁴Schaffhausen, CR, Marilyn J. Bruin, MJ., Warren T. McKinney, WT, Snyder, J., Matas, AJ, Kasiske, BL, Bisran, AK. [How patients choose kidney transplant centers: A qualitative study of patient experiences](#). Clin.Transplantation. Volume33, Issue5. May 2019. (abstract) (indicating that patient choice often determined by referrals by trusted provider, insurance coverage, reputation, comfort, and convenience).

⁵Snyder JJ, Salkowski N, Kim SJ, Zaun D, Xiong H, Israni AK, et al. Developing Statistical Models to Assess Transplant Outcomes Using National Registries: The Process in the United States. Transplantation 2016;100(2):288–94. [PubMed: 26814440]

⁶Jesse D. Schold, Kenneth A. Andreoni, Anil K. Chandraker, Robert S. Gaston, Jayme E. Locke, Amit K. Mathur, Timothy L. Pruett, Abbas Rana, Lloyd E. Ratner, Laura D. Buccini, [Expanding clarity or confusion? Volatility of the 5-tier ratings assessing quality of transplant centers in the United States](#). American Journal of Transplantation. 09 January 2018.

⁷Wey, Andrew & Salkowski, Nicholas & Kasiske, Bertram & Skeans, Melissa & Schaffhausen, Cory & Gustafson, Sally & Israni, Ajay & Snyder, Jon. (2018). [Comparing Scientific Registry of Transplant Recipient posttransplant program-specific outcome ratings at listing with subsequent recipient outcomes after transplant](#). American Journal of Transplantation. 19. 10.1111/ajt.15038.

ratings changed experienced at least one negative consequence of the star ratings, such as loss of patients, loss of referrals, or loss of payer contracts.⁸

There are a number of donor risk factors for which there is moderate to high certainty in the magnitude of association with 1-year graft loss, including donor age, extended criteria donors, deceased (vs. living) donors, and a number of additional variables for which, with moderate certainty, there is an association with 1-year graft loss, including donor sex and donor BMI.⁹ In light of the adverse significant financial repercussions that a TC may experience as the result of a negative change in the TC's star ratings, and the volatility of the system, so long as the five-year rating methodology remains unchanged, TCs are highly unlikely to change risk averse patient selection and organ acceptance patterns, significantly reducing the likelihood of success of CMS efforts to increase OPO transplantation rates as anticipated by the new OPO conditions for certification.

b. OPTN/MPSC TC Performance Reviews

In addition to the star ratings, the procedures used by the OPTN to conduct TC performance evaluations create additional disincentives for TCs to accept organs viewed as "marginal" or to transplant older and less healthy recipients. Flagging may trigger quasi-legal proceedings potentially resulting in a public announcement that a TC is "on probation" or is a "Member Not In Good Standing." The unintended consequences resulting from the OPTN/MPSC process used to "flag" low performing (LP) TCs, including the impact on the number of transplants performed by TCs identified as LP are described at length in a 2017 article published by Drs. Jay and Schold, *Measuring transplant center performance: The goals are not controversial but the methods and consequences can be*,¹⁰ which concludes, with multiple citations to the clinical literature, that "Numerous studies have demonstrated the relationship between "flagging" or of Low Performing evaluations and changes in transplant volume." It also appears that outcomes-based performance reviews may incentivize TCs to remove less healthy patients from their waiting lists.¹¹

An additional bibliography of relevant references is included as Attachment D.

Request

Based on this data, we believe that it is clear that the outcomes-related measures currently used by the OPTN to trigger TC performance review and the outcomes-related star ratings included in TC program-related reports materially interfere with the objectives sought to be achieved by CMS' reform of the OPO certification requirements and other actions taken by CMS to increase the availability of transplantation.

We request a joint meeting with CMS/CCSQ and HRSA/Healthcare Systems Bureau/Division of Transplantation to reconcile the conflicting incentives discussed above. We also urge CMS to request

⁸Van Pilsum Rasmussen SE, Thomas AG, Garonzik-Wang J, Henderson ML, Stith SS, Segev DL, Nicholas LH. Reported effects of the Scientific Registry of Transplant Recipients 5-tier rating system on US transplant centers: results of a national survey. *Transpl Int*. 2018 Oct;31(10):1135-1143. doi: 10.1111/tri.13282. Epub 2018 Jun 10. PMID: 29802802; PMCID: PMC6219856.

⁹Farid Foroutan, Erik Loewen Friesen, Kathryn Elizabeth Clark, Shahrzad Motaghi, Roman Zyla, Yung Lee, Rakhshan Kamran, Emir Ali, Mitch De Snoo, Ani Orchanian-Cheff, Christine Ribic, Darin J. Treleaven, Gordon Guyatt, Maureen O. Meade. [Risk Factors for 1-Year Graft Loss After Kidney Transplantation](#). *CJASN* Nov 2019, 14 (11) 1642-1650; DOI: 10.2215/CJN.05560519.

¹⁰Jay, C, Schold, JD. [Measuring transplant center performance: The goals are not controversial but the methods and consequences can be](#). *Curr Transplant Rep*. 2017 March ; 4(1): 52–58. doi:10.1007/s40472-017-0138-9.

¹¹J.D. Schold, L. D. Buccini, E.D. Pogglo, Association of Candidate Removals from the Kidney Transplant Waiting List and Center Performance Oversight. *American Journal of Transplantation* 2016; 16: 1276-1284.

HRSA to review the continued need for these outcomes-based metrics in light of their unanticipated consequences and to explore alternative methodologies for TC performance evaluation. We are aware that the OPTN/MPSC is currently considering the metrics that should be used in conducting TC performance reviews and, for this reason, such a request would be extremely timely.

If you have any questions regarding ASTS' position on this issue, please do not hesitate to contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870.

Sincerely,



Marwan S. Abouljoud, MD, FACS, MMM
President
American Society of Transplant Surgeons

Cc:

David R. Wright, Director, Quality and Safety Oversight Group (QSOG)
Lisa M. Parker, Acting Director, Clinical Standards Group
Maria L. Hammel, Director, Division of Non-Institutional Quality Standards
Alpha Banu Wilson, Health Insurance Specialist, CCSQ
Jesse L. Roach, MD, CCSQ, Quality Measurement & Value Based Incentives Group
Karen L. Tritz, Acting Director, Survey and Operations Group
Twyla Griffin, Special Assistant, CMS
Jessica Wright, Special Assistant, QSOG
Adam C. Richards, Health Specialist, CMS, CCSQ,
Danielle Shearer, Acting Director, Division of Institutional Quality Standards
Diana Espinosa, MPP, Acting Administrator, HRSA
Cheryl R. Dammons, Associate Administrator, Healthcare Systems Bureau, HRSA
Frank Holloman, Director, Division of Transplantation, HSB, HRSA

Attachment A

ASTS Statement on Islet Cell Transplantation Regulations

Drafted by Piotr Witkowski, MD, PhD and approved by the ASTS Executive Committee, December 23, 2020

The issue of declining islet cell transplantation and over regulation emerged from ASTS member Dr. Witkowski.

Definition of the Problem:

Islet allotransplantation in the United States (US) is facing an imminent demise, leaving patients with type 1 diabetes mellitus (T1DM) and severe hypoglycemia without access to a lifesaving therapeutic procedure.

The safety and effectiveness of allo-islet transplantation has been established in NIH-sponsored U.S. clinical trials as well as through the Collaborative Islet Transplantation Registry, U.S. taxpayer-funded research projects, which collectively have analyzed data from more than 2,000 allo-ITx procedures over the past 20 years.

However, despite decades of progress in the field driven by U.S. academic centers, an archaic regulatory framework has stymied U.S. clinical practice. Current Food and Drug Administration (FDA) requirements for allogeneic islets for transplantation do not reflect the clinical or technical state-of-the-art.

- Autologous islets (*auto-islets*) **and** allogeneic islets (*allo-islets*) are sourced and processed identically, but are subject to vastly different FDA regulatory requirements:
 - Auto-islets, like many tissue- and cellular-based products, are subject to limited requirements aimed at ensuring appropriate collection, storage, processing, and distribution (**Section 361** Public Health Service (PHS) Act).
- Allo-islets, in contrast, are subject to much more extensive requirements because they are categorized as biological products (**section 351** PHS Act and Federal Food, Drug and Cosmetics Act).
- The distinction between auto- and allo-islets based on criteria established nearly 30 years ago (21 CFR Part 1271) do NOT reflect current standards and clinical practice. As a consequence, there has been significant impact on allo-islet transplantation effectively preventing its therapeutic use in the U.S.
 - In the past four years, only 11 patients have undergone allogeneic islet transplantation (allo-ITx) in the U.S., all under an investigational protocol. In contrast, in Europe, Canada, Australia, and Japan, islets are NOT regulated as a drug and allo-ITx is a standard-of-care procedure annually benefiting hundreds of patients with type 1 diabetes.
- Allo-islets in the U.S. require premarket approval of a biologics license application (BLA) and extensive post-market compliance obligations. The FDA's requirements are geared to commercial manufacturers of drug products, and not to clinical transplant centers. Only a commercial (pharma/biotech) company realistically could comply with these requirements. Regulating transplant centers as drug manufacturers and requiring premarket approval for allo-islets effectively

precludes clinical transplant centers from offering allo-ITx to patients, and preventing optimal patient care.

- The first commercial entity to obtain FDA approval of a BLA for allo-islets will be eligible for seven years of market exclusivity, further limiting patient access to the therapy. The price for FDA-approved allo-islets produced by a commercial manufacturer foreseeably will be significantly inflated to recover enormous costs associated with preparing a BLA and complying with the manufacturing regulations for commercial drugs. The absence of competition, at least initially, will also escalate the price and discourage innovations in islet processing, to the detriment of patients who could benefit from this life-saving therapy.
- Allowing the commodification of islets runs counter to the ethical norms underlying the organ and tissue transplantation framework, under which the sale of organs and tissues is prohibited and organ donation is viewed as an altruistic act.

The Solution:

We propose to harmonize the U.S. approach to allo-ITx with that of many other countries, which would allow for implementation of safe, effective, affordable, and widely accessible islets for transplantation as a standard of care procedure.

- Specifically, we seek urgent modification of the FDA regulatory status of allo-islets, before a BLA is issued and orphan designation is awarded to a single commercial sponsor (which could happen as soon as March 2021).
- Allo-islet regulation should be consistent with the regulation of auto-islets and other minimally-manipulated human tissue for transplantation.

We recommend that the FDA:

1. Confirm islet allografts are “minimally manipulated” HCT/Ps as that term is defined in FDA regulations, because they are subject to only short-term incubation prior to allograft infusion that does not alter their relevant biological characteristics.
2. Allow allogeneic islets from unrelated donors to be eligible for regulation as HCT/Ps exclusively under Section 361/Part 1271, provided that donors and recipients are immunologically compatible as determined by current clinical standards for immunological matching in organ and tissue transplantation.

We recommend that HRSA, through the United Network for Organ Sharing (UNOS)/Organ Procurement and Transplantation Network (OPTN), continue to oversee pancreas allocation and procurement and extend its oversight of transplant programs to include those that perform islet transplantation, which would allow HRSA to monitor the outcomes of patients receiving allo-ITx.

The Conclusion:

Allo-islets is a “poster child” for archaic over-regulation. Adjusting the regulation would remove regulatory barriers, reflect our current clinical practice, and deal with our upcoming challenge. ASTS proposes the forementioned updates to current regulations as critical for the renaissance of ethical, safe, effective, and affordable allo-ITx in the United States.

Attachment B

Additional Transplants Necessary to Reach Targets

OPO Name (Primary State)	Actual Transplants (2018)	Median	Top 25%	Add'l Tx to Meet Target
Tennessee Donor Services (TNDS)	922	0	2	0%
LifeChoice Donor Services (CTOP)	221	0	4	2%
Sierra Donor Services (CAGS)	239	0	7	3%
New Jersey Sharing Network OPO (NJTO)	538	0	15	3%
Louisiana Organ Procurement Agency (LAOP)	604	0	23	4%
ConnectLife (NYWN)	134	0	7	5%
LifeLink of Georgia (GALL)	898	0	75	8%
Pacific Northwest Transplant Bank (ORUO)	401	0	36	9%
Lifeline of Ohio (OHLP)	410	0	47	11%
Center for Donation and Transplant (NYAP)	145	0	18	12%
LifeSource - MN (MNOP)	572	0	71	12%
Iowa Donor Network (IAOP)	247	0	32	13%
OneLegacy (CAOP)	1,625	0	202	12%
Legacy of Hope - Alabama (ALOB)	472	12	75	16%
Mississippi Organ Recovery Agency (MSOP)	264	8	44	17%
Donor Alliance (CORS)	491	15	81	16%
Texas Organ Sharing Alliance (TXSA)	574	31	110	19%
Life Connection of Ohio (OHLC)	233	17	50	21%
Sharing Hope SC (SCOP)	555	42	120	22%
LifeNet Health (VATB)	521	44	117	22%
Finger Lakes Donor Recovery Network (NYFL)	188	19	47	25%
LifeCenter Organ Donor Network (OHOV)	232	26	60	26%
Arkansas Regional Organ Recovery Agency (AROR)	208	25	56	27%
Carolina Donor Services (NCNC)	638	80	173	27%
LifeQuest Organ Recovery Services (FLUF)	482	63	134	28%
Legacy of Life (HIOP)	95	20	35	37%
New Mexico Donor Services (NMOP)	136	29	51	38%
Indiana Donor Network (INOP)	636	135	236	37%
Kentucky Organ Donor Affiliates (KYDA)	454	110	184	41%
Life Alliance Organ Recovery Agency (FLMP)	493	130	211	43%
Mid-South Transplant Foundation (TNMS)	196	109	149	76%
Subtotal of Transplants Plus Pancreata Research	33,431	915	2,472	
Total Actual Transplants	32,852	899	2,429	

Attachment C

ASTS Recommendations for Optimization of Transplant Center Assessment

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.

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 2019.¹² 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.¹³ 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.

¹²Buccini L, Segev D, Fung J, et al. Association between liver transplant center performance evaluations and transplant volume: potential unintended consequence of quality oversight. *Transplantation*. 2014;98:204.

Axelrod DA. Balancing accountable care with risk aversion: transplantation as a model. *Am J Transplant*. 2012;13(1):7-8.

Schold JD, Howard RJ. Prediction models assessing transplant center performance: can a little knowledge be a dangerous thing? *Am J Transplant*. 2006;6(2):245-246.

Schold JD, Nicholas LH. Considering potential benefits and consequences of hospital report cards: what are the next steps? *Health Serv Res*. 2015;50(2):321-329.

Schold JD, Buccini LD, Poggio ED, Flechner SM, Goldfarb DA. Association of candidate removals from the kidney transplant waiting list and center performance oversight. *Am J Transplant*. 2016;16(4):1276-1284.

¹³Bowring MG, Massie AB, Craig-Schapiro R, Segev DL, Nicholas LH. Kidney offer acceptance at programs undergoing a Systems Improvement Agreement. *Am J Transplant*. 2018;18(9):2182-2188.

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.¹⁴ *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.

¹⁴Bowring MG, Massie AB, Craig-Schapiro R, Segev DL, Nicholas LH. Kidney offer acceptance at programs undergoing a Systems Improvement Agreement. *Am J Transplant.* 2018;18(9):2182-2188.

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."¹⁵

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."

¹⁵<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

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.¹⁶ ASTS believes that OPTN/MPSC

¹⁶<https://optn.transplant.hrsa.gov/governance/strategic-plan/goal-1/>

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 to 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 to 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.

Attachment D

References:

1. Tonelli M, Wiebe N, Knoll G, et al. [Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes](#). Am J Transplant. 2011; 11: 2093-2109.
2. Axelrod DA, Schnitzler MA, Xiao H, et al. [An economic assessment of contemporary kidney transplant practice](#). Am J Transplant. 2018;18: 1168–76.
3. Waterman AD, Peipert JD, Xiao H, et al. [Education Strategies in Dialysis Centers Associated with Increased Transplant Wait-listing Rates](#). Transplantation 2020; 104(2):335-342.
4. Waterman AD, Peipert JD, Goalby CJ, Dinkel KM, Xiao H, Lentine KL. [Assessing Transplant Education Practices in Dialysis Centers: Comparing Educator Reported and Medicare Data](#). Clin J Am Soc Nephrol. 2015; 10: 1617–25.
5. U.S. Department of Health & Human Services. Advancing American Kidney Health. Available at:<https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>. (Accessed: January 12, 2021).
6. Lentine KL, Mannon RB. [The Advancing American Kidney Health \(AAKH\) Executive Order: Promise and Caveats for Expanding Access to Kidney Transplantation](#). Kidney360 2020 Jun;1(6):557-560.
7. Bieber SD and Gadegbeku CA. [A Call to Action for the Kidney Community. Nephrologists' Perspective on Advancing American Kidney Health](#). CJASN 2019; 14: 1799–1801.
8. Andrea Tietjen A, Hays R, McNatt G, et al. [Billing for living kidney donor care: Balancing cost recovery, regulatory compliance, and minimized donor burden](#). Curr Transplant Rep. 2019 Jun; 6(2): 155–166.
9. S Gill JS, Wiseman A. [Bandages will not fix a fractured system of chronic kidney disease care: Why the Dialysis PATIENTS Demonstration Act cannot be supported by the transplant community](#). Am J Transplant. 2019 Apr;19(4):973-974.
10. Patzer RE, Plantinga LC, Paul S, et al. [Variation in dialysis facility referral for kidney transplantation among patients with end-stage renal disease in Georgia](#). JAMA. 2015;314(6):582-594.
11. Hamilton TE. [Regulatory oversight in transplantation: are the patients really better off?](#) Curr Opin Organ Transplant. 2013 Apr;18(2):203-9. doi: 10.1097/MOT.0b013e32835f3fb4. PMID: 23429659.
12. Woodside KJ, Sung RS. [Do Federal Regulations Have an Impact on Kidney Transplant Outcomes?](#) Adv Chronic Kidney Dis. 2016 Sep;23(5):332-339. doi: 10.1053/j.ackd.2016.09.001. PMID: 27742389.
13. Schold JD, Patzer RE, Pruett TL, Mohan S. [Quality Metrics in Kidney Transplantation: Current Landscape, Trials and Tribulations, Lessons Learned, and a Call for Reform](#). Am J Kidney Dis. 2019 Sep;74(3):382-389. doi: 10.1053/j.ajkd.2019.02.020. Epub 2019 Apr 23. PMID: 31027881.
14. Ouayogodé MH. [Quality-based ratings in Medicare and trends in kidney transplantation](#). Health Serv Res. 2019 Feb;54(1):106-116. doi: 10.1111/1475-6773.13098. Epub 2018 Dec 5. PMID: 30520027; PMCID: PMC6338323.
15. Howard RJ, Cornell DL, Schold JD. [CMS oversight, OPOs and transplant centers and the law of unintended consequences](#). Clin Transplant. 2009 Nov-Dec;23(6):778-83. doi: 10.1111/j.1399-0012.2009.01157.x. PMID: 20447183.
16. Wey A, Salkowski N, Kasiske BL, Israni AK, Snyder JJ. [A Five-Tier System for Improving the Categorization of Transplant Program Performance](#). Health Serv Res. 2018 Jun;53(3):1979-1991. doi: 10.1111/1475-6773.12726. Epub 2017 Jun 13. PMID: 28608369; PMCID: PMC5980219.
17. Van Pilsum Rasmussen SE, Thomas AG, Garonzik-Wang J, Henderson ML, Stith SS, Segev DL, Nicholas LH. [Reported effects of the Scientific Registry of Transplant Recipients 5-tier rating system on US transplant centers: results of a national survey](#). Transpl Int. 2018 Oct;31(10):1135-1143. doi: 10.1111/tri.13282. Epub 2018 Jun 10. PMID: 29802802; PMCID: PMC6219856.
18. White SL, Zinsser DM, Paul M, Levine GN, Shearon T, Ashby VB, Magee JC, Li Y, Leichtman AB. [Patient selection and volume in the era surrounding implementation of Medicare conditions of](#)

[participation for transplant programs](#). Health Serv Res. 2015 Apr;50(2):330-50. doi: 10.1111/1475-6773.12188. Epub 2014 May 19. PMID: 24838079; PMCID: PMC4369212.

19. Bello AK, Alrukhaimi M, Ashuntantang GE, Bellorin-Font E, Benghanem Gharbi M, Braam B, Feehally J, Harris DC, Jha V, Jindal K, Johnson DW, Kalantar-Zadeh K, Kazancioglu R, Kerr PG, Lunney M, Olanrewaju TO, Osman MA, Perl J, Rashid HU, Rateb A, Rondeau E, Sakajiki AM, Samimi A, Sola L, Tchokhanelidze I, Wiebe N, Yang CW, Ye F, Zemchenkov A, Zhao MH, Levin A. [Global overview of health systems oversight and financing for kidney care](#). Kidney Int Suppl (2011). 2018 Feb;8(2):41-51. doi: 10.1016/j.kisu.2017.10.008. Epub 2018 Jan 19. PMID: 30675438; PMCID: PMC6336220.