American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

February 1, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244-8010

Re: [CMS–3409–NC]; RIN 0938–AU55; Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities ("Request for Information" or "RFI")

Administrator Brooks-LaSure:

On behalf of the American Society of Transplant Surgeons (ASTS), we appreciate your leadership in advancing the agency's recent Request for Information (RFI). 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.

ASTS shares your passion and devotion to improving systems of transplant for patients and hope that our RFI response will serve as a roadmap to a collaborative partnership with all related agencies to promote transplantation and better serve transplant patients. We organized our comments under the following topics and provided suggested recommendations under each topic area:

BETTER GOVERNMENT COORDINATION AND TRANSPARENCY OF SYSTEM GOALS

- Intra-Agency and Intra-Departmental Coordination of Policies Related to Organ Donation and Transplantation, Including Transparency of Transplant Goals
- Elimination of Duplicative Regulation of Transplant Programs
- Alignment of Outcomes Expectations

BETTER USE OF SCARCE RESOURCES

- Transplant Center Outcomes
- Organ Discards

BETTER PATIENT CARE AND TRANSPARENCY

- Transplant Quality
- Conditions of Participation
- Transplant Recipient Patient Rights (Increasing Transparency)

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IMPROVING EQUITY IN ORGAN DONATION AND TRANSPLANTATION

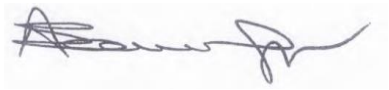
- Equity in Organ Transplantation and Organ Donation
- Organ Acquisition and Organ Recovery Centers

INCREASING ORGAN AVALABILITY AND TRANSPLANT RESEARCH

- Increasing Donor Identification and the Number of Potential Organs Available for Transplantation
- Donation after Cardiac Death
- Development of New Treatments and Technologies

We hope that your efforts will propel us into ongoing discussions about the critical issues facing transplant providers and patients. In short, we strongly believe that we can work together to ensure that patients get the benefit of new or revised transplant policies that are more efficient, patient-focused, transparent, and effective in ensuring the best transplant care for all Americans.

Sincerely yours,



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

BETTER GOVERNMENT COORDINATION AND TRANSPARENCY OF SYSTEM GOALS

The RFI solicits comments on how to harmonize requirements across government agencies to facilitate greater access to transplantation and improve quality across the organ donation and transplantation ecosystem. There is a critical need for such harmonization and improved coordination both among various CMS offices and within the various divisions of HHS to achieve the laudable objectives described in the RFI.

We believe that these efforts at improved coordination should prioritize four critical areas:

- Setting transparent system goals,
- Aligning transplant-related policy department-wide,
- Reducing duplicative regulation of Transplant Programs by the Health Resources and Services Administration (HRSA) and CMS; and,
- Eliminating regulatory disincentives to transplantation, including regulatory disincentives to the acceptance of hard to place organs.

Intra-Agency and Intra-Departmental Coordination of Policies Related to Organ Donation and Transplantation, Including Transparency of Transplant Goals

A number of offices and agencies (CMS, HRSA, FDA, NIH,CDC, HRSA contractors, the OPTN and SRTR, and the Advisory Committee on Organ Transplantation (ACOT)) both within and outside of HHS and CMS regulate, fund, or otherwise impact various aspects of transplantation. Unfortunately, under current organizational structure, there is no centralized authority for establishing department-wide goals and policies to guide the direction of all the various governmental agencies. We believe that the establishment of a structure at the level of the Office of the Secretary of HHS would go a long way toward achieving the objectives outlined in the RFI.

We believe that coordination could be improved significantly. For example:

- The sources of funding for transplant-related research at the NIH are inadequate and fragmented. Transplant-related research is not a declared NIH priority, nor is there a research-based solution for increasing the use of hard to place organs.

- CMS issued a notice of proposed rulemaking last year (since tabled) that would have slashed Medicare payment for Organ Acquisition Costs and the number of organs recovered.

- While CMS issued new OPO Conditions of Coverage (CfC) that clearly incentivize the procurement of pancreata for islet transplantation, FDA regulatory requirements limit the development of this field.

- While dialysis facility quality requirements encourage dialysis facilities to get their patients on transplant program waitlists, the five-star rating system ("Time to Transplant") and the new OPTN transplant program waitlist mortality performance metrics incentivize transplant programs to institute stricter criteria for waitlist inclusion and maintenance of potential recipients on the waitlist.

- CMS policy disallows Medicare payment for the cost involved in transporting a donor to an Organ Recovery Center (ORC) where efficient organ procurement facilitates increased organ recovery.

- The current Medicare cost report structure disincentivizes transplant hospitals to transfer deceased donors from transplant hospitals to OACs due to lost revenue for donor charges that could normally be billed through the Medicare cost report.

RECOMMENDATION: In order to achieve integrated oversight of transplantation and to improve access, equity, and innovation for the benefit of our patients, the Office of the Secretary of the Department of Health and Human Services should convene an Intra-Agency Coordinating Council including all agencies, departments, and divisions that oversee transplantation (including representatives of CMS, HRSA, OPTN, CDC, NIH, and the FDA). Under the auspices of the Office of the Secretary, and with the input of the transplant community, the Intra-Agency Coordinating Committee should set public, defined goals for the transplant eco-system that guide policy and oversight, optimize organ placement logistics, stimulate innovation and research, and remove disincentives to transplantation. The system goals should be updated on a biannual or triannual basis and the coordinating committee should maintain a public score card of progress toward these goals.

Elimination of Duplicative Regulation of Transplant Programs

We also urge HHS to prioritize elimination of duplicative regulatory requirements that stand in the way of patient care. CMS and HRSA regulation of transplant programs are highly duplicative, and the volume of regulations presents an extraordinary regulatory burden that diverts transplant teams' attention from patient care, clinical quality improvement, educational and outreach efforts, and innovation. Both agencies regulate transplant organization and operation "from soup to nuts," including pre-transplant, transplant, and post-transplant phases. Notably,

- The OPTN regulatory requirements include 230 pages of policy, 180 pages of Bylaws, and 65 pages of Evaluation Plan.

- CMS regulatory requirements include 85 pages of the Federal Register, 107 pages of the Survey and Certification Interpretive Guidelines, 50 pages of Survey and Certification Interpretive Guideline Changes, 49 pages of Quality Assessment and Performance Improvement (QAPI) Program requirements, 103 pages of updated Interpretive Guidelines, and numerous additional updates and clarifications.

Duplicative regulation of transplant programs is a historical anomaly resulting from the OPTN's regulatory oversight role of transplant programs prior to the adoption of the Medicare Conditions of Participation (CoP). Both the OPTN and CMS have the same policy goals regarding transplant program oversight – to ensure that transplant-related services adhere to high quality standards and are provided safely and equitably. For example, consider regulations related to the Independent Donor Advocate (ILDA):

- The most recent version of CMS' COP Interpretive Guidelines, published May 24, 2019, directs the ILDA or independent Donor Advocate Team (ILDAT) to interview all potential living donors

prior to the initiation of the evaluation and prior to performing any type of donor screening such as blood type.

- This guideline has led to a large investment of time and energy on behalf of the potential donor and the ILDA to interview donors who may not be the right blood type or height/weight to proceed and could have easily been spared this interview.

- OPTN has extensive policies covering ILDA and living donation; however, there is no similar mandate in the OPTN policies that mirrors the ILDA requirement in CMS' Interpretive Guidelines.

RECOMMENDATION: ASTS urges HHS and CMS to simplify and streamline transplant program regulatory oversight by creating the following streamlined, coordinated structure[1]:

- **One set of Transplant Center oversight regulations and regulatory interpretations,**
- **One set of TC outcome measures to be used solely for identifying Transplant Programs for confidential peer review by the OPTN's Membership Performance and Standards Committee (MPSC),**
- **One combined survey conducted as necessary based on a single set of survey triggers,**
- **One process of enforcement.**

In implementing this objective, consideration should be given to a division of responsibility under which:

- OPTN regulatory oversight focuses on those tasks specifically enumerated by the National Organ Transplant Act (NOTA) and implementing regulations (the "Final Rule").
    - These generally include activities that take place outside the walls of the Transplant Center including, for example, organ acquisition, transportation, allocation, and organ acceptance practices.
    - OPTN oversight of activities within the walls of the Transplant Center should be structured as non-regulatory peer review, and the implementing regulations should be modified to ensure the confidentiality of the OPTN's peer review processes without regard to variation in state peer review protections.

Undertaking such a bold initiative could be achieved by a thorough review of overlapping regulations conducted by the Office of the Secretary, dividing responsibilities among the various entities involved with the goal of reducing duplicative and overly prescriptive regulation.

Alignment of Outcomes Expectations

Transplant outcomes of graft and patient survival in these modern times are so good despite the increased complexity and severity of illness of patients with end-stage organ failure, that small percentage differences in the current metrics that may be statistically significant should not trigger regulatory actions that interfere with patients' access to transplantation.

[1] Attachment A: ASTS Letter to HHS Secretary Price, Sept. 11, 2017.

Regulatory metrics are complex and have significant unintended consequences. For example, it is well recognized that the OPTN one-year outcome metrics, along with the SRTR five-star public ratings, do not allow patients to achieve optimal transplant opportunities. These metrics and the risk of public flagging disincentivize transplant programs from accepting organs at risk of discard and from transplanting older and medically complex recipients. The available clinical literature strongly supports that transplant programs flagged by the OPTN Membership and Professional Standards Committee (MPSC) for performance review curtail transplantation. In light of the large number of potential transplant recipients who die awaiting a life-saving transplant, it is clear that CMS' goal of enhancing patient safety is best served by eliminating disincentives to transplantation.

In addition, the newly approved OPTN MPSC performance review criteria do not further the cause of patient safety as both waitlist mortality and organ acceptance rates depend on multiple geographic, clinical, and organ distribution issues that are not captured by current data. We are concerned that these metrics have the potential to increase, rather than reduce, risk aversive patient and organ selection; and to reduce, rather than increase, the number of clinically appropriate transplants performed. We also are concerned that applying multiple regulatory metrics concomitantly has the potential to curtail transplants for patients in the U.S.

The need for better alignment between CMS, HRSA, the OPTN, and SRTR is most acute with respect to transplant program performance standards. As noted above and as we discuss in the section of the comments that address outcomes and discards, current and proposed outcomes metrics are an important factor contributing to *risk aversion and reluctance to accept hard to place organs* among some transplant programs. Adding to the regulatory dilemma, consider the following divergent approaches:

- CMS appropriately eliminated outcomes requirements as a condition of recertification, recognizing that these requirements contribute to risk aversion among transplant centers.

- The OPTN recently doubled the number of outcomes requirements and added new pre-transplant and organ acceptance metrics that, in our view, are likely to exacerbate the risk averse behavior adopted by some transplant programs.

- The SRTR adopted a wholly different model than either CMS or the OPTN, consisting of a five-star rating system that does not reflect a meaningful difference in transplant outcomes but unfortunately has been adopted, inadvertently, by many U.S. insurance companies to determine whether they will include centers within their networks, further threatening access to transplantation. SRTR metrics were not intended for this purpose or for program performance assessment; rather, they were designed as a patient facing metric to guide selection by patients.

- The SRTR formulated, and HRSA approved,[2] a methodological modification to account for COVID-19's impact on transplant recipient outcomes (and therefore program performance ratings). This change, which was adopted without opportunity for public comment, has the potential to result in the exclusion of transplant programs from private payer networks if they experienced COVID peaks after the first three months of the pandemic, or if they serve an

[2] Our discussions with HRSA on these issues suggest that HRSA takes the position that its role in SRTR and OPTN policy decisions is limited to ensuring that these policies are consistent with NOTA and the applicable regulatory requirements.

unusual number of minority patients, whose COVID-related mortality rate is disproportionately high. Transplant outcomes during this ongoing pandemic are multifactorial and impacted by many biological, geographical, political, social, behavioral, economic, and workforce related factors beyond the control of transplant centers and should not be interpreted as indicators of center performance or as quality metrics.

- HRSA recently contracted with the SRTR to examine transparency in transplantation and is planning a consensus conference for later this year, which is expected to address public transplant program performance measures, among other issues. While we welcome and plan to participate in a conversation about improving transparency, we are concerned that we could again face the possibility of the addition of overlapping, duplicative, or potentially conflicting metrics or reporting requirements stemming from bifurcated public reporting mandated by HRSA/SRTR and CMS.

RECOMMENDATION: CMS, HRSA, the OPTN, and SRTR must re-assess transplant metrics to ensure increased transplantation, improved organ utilization, increased innovation, and reduced risk aversion. We encourage these agencies to speak with one voice with respect to transplant program outcomes and other performance expectations. Any policies relating to transplant program performance should be coordinated through the Intra-Agency Coordinating Committee described above and should be developed with experts in the field and include a mechanism for public input, periodic reassessment of validity, and any unintended consequences.

BETTER USE OF SCARCE RESOURCES

Transplant Center Outcomes

Outcomes Requirements

We strongly agree that transplantation should be more accessible and equitable. Increased access to transplantation has the potential to transform lives and to substantially reduce Medicare expenditures for ESRD-eligible patients. While CMS has wisely recognized that the emphasis on transplant outcomes inhibits this goal, the continued focus on outcomes reflected in OPTN and SRTR five-star ratings remains a significant factor in stifling innovation and in curtailing patient access to transplantation. Linking outcome measures to regulatory consequences has become a major disincentive to transplantation by driving transplant programs to be risk averse, both with respect to waitlisting and to organ acceptance decisions.

To understand why this is so, consider the following chart, which reflects kidney transplant one-year outcomes based on the most recently available SRTR report[3]:

Star Ratings					
1-Year kidney Survival (% with functioning transplant at 1 year)	**91**	**94**	**95**	**96**	**97**

A "three bar" rating indicates that a transplant program has outcomes "as expected:" Therefore, a transplant program with a "three bar" rating (often required for participation in third party payer networks) is disincentivized to accept any deceased donor kidney (or any potential recipient) that could result in even a slight reduction in patient or graft survival (from 95% to 94% graft survival).

The fact that organ quality may significantly impact outcomes is uncontroverted, and while the SRTR risk adjustment methodology considers several donor characteristics, the risk model changes with each assessment cycle impacting programs in an unpredictable way. Nearly every program is clustered around the high bar required to remain in compliance with OPTN policy and satisfactory star ratings. Because the models change, it is not possible to know if accepting an increased risk organ or patient will impact a transplant center's performance assessment or if so, how.

The overall extraordinary success of transplantation is also a major factor. Program-specific outcomes data for a recent reporting period suggests that an estimated 63% of programs with three stars ("as expected" outcomes) had 100% one-year graft survival (rounded to the nearest percent). How likely is such a center to take the risk of accepting a hard to place organ, not knowing if an adverse outcome could result in a two-star rating and loss of private payer coverage? Considering the significantly higher

[3] These outcomes are particularly extraordinary when considered in relation to mortality rates for other types of major surgery. Khuri SF, Henderson WG, DePalma RG, et al. Determinants of long-term survival after major surgery and the adverse effect of postoperative complications. *Ann Surg*. 2005;242(3):326-343. doi:10.1097/01.sla.0000179621.33268.83. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1357741/.

"expected" graft survival of living donor kidneys (which for many programs exceeds 98.5 %), a transplant program may incur regulatory risk – and the risk of losing Center of Excellence status that is critical for third party payer network inclusion – when it performs a living donor transplant for anyone but the healthiest of recipients. Considering that geriatric and high-risk patients are limited in their ability to tolerate the number of years on dialysis and the waitlist that is necessary to receive a transplant, these inflated outcome requirements can significantly limit their access to living donation. Under these circumstances, it is hardly surprising that CMS' elimination of outcomes requirements for transplant program re-certification alone will be sufficient to substantially impact the rate of transplantation.

RECOMMENDATION: We urge CMS to work with HRSA, the OPTN, and the SRTR to eliminate the disincentives to transplantation created by current outcomes and other performance evaluation criteria used by the OPTN and in the SRTR five-star ratings.[4]

At this stage, one-year outcomes have been utilized as a basis for transplant program performance for over 15 years and we see a trend to add more metrics in an attempt to modify transplant program behavior. For many reasons cited above, we believe that the current and proposed metrics all can and potentially will lead to further restricting access to transplantation; particularly since the OPTN aspires to set the triggering thresholds at a level that maintains the percent of programs undergoing public flagging as unchanged and despite the available literature documenting the negative impact of public flagging on center volume and transplantation rate. The need to have a defined number of programs flagged on a regular basis is not a sound quality principle and seems arbitrary. In our view, what is needed now is a 'reset' of outcomes performance expectations – a major signal to encourage transplant programs to focus attention on outreach, education, research, innovation and to abandon risk aversive patient and organ selection.

RECOMMENDATION: CMS, HRSA, the OPTN and the SRTR should work together to implement a pilot project that modifies performance evaluation criteria to eliminate or mitigate their impact on transplant access, innovation, and organ utilization. Such a pilot program might, for example, exclude hard to place kidneys from outcomes measurement; might provide public credit for programs that successfully utilize hard to place organs; might provide a financial incentive to programs that achieve excellence in the transplantation of these organs; might exclude from outcomes measures transplants performed under research protocols approved by the NIH or a designated transplant central IRB; or might eliminate outcomes assessment if a transplant program's post-surgical graft survival for hard to place kidneys exceed a specified predetermined fixed level.

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[4] ASTS Recommendations for Optimization of Transplant Center Assessment, January 2021, ASTS Statement on OPO Metrics, September 2020, SRTR presentation on Task 5, Sept. 2021, NASM statement July 2021, Joint Statement on CfCs, March 2021, ASTS Comments on OPO Conditions for Coverage, March 2021, and see
Attachment A: ASTS Letter to HHS Secretary Tom Price, Sept. 11, 2017.
Attachment B: ASTS Presentation for HRSA/CMS Joint Meeting, March 17, 2021
Attachment C: ASTS Letter to HRSA Acting Administrator Diana Espinosa, February 2021
Attachment D: ASTS Presentation for Meeting with HRSA Administrator Thomas Engels, February 7, 2020
Attachment E: ASTS Presentation to HRSA Administrator George Sigounas, May 3, 2018
Attachment F: Letter to Daniel Schwartz, MD and James Cowher, CDR, USPHS, June 25, 2019

Another unintended consequence of the widespread utilization of the OPTN outcome measures and the SRTR star ratings is the potential for limiting access of Medicare beneficiaries. With Medicare allowing more dialysis patients the opportunity to join Medicare advantage plans, there is a risk that administrators of these plans will start limiting access of programs based on their star ratings.

RECOMMENDATION: We also urge HHS and CMS to encourage Medicare Advantage plans, exchange plans, and other health plans under their jurisdiction to refrain from excluding transplant programs from their networks based on a Transplant Program's star rating or other outcomes assessment, so long as they have acceptable OPTN survival outcomes.

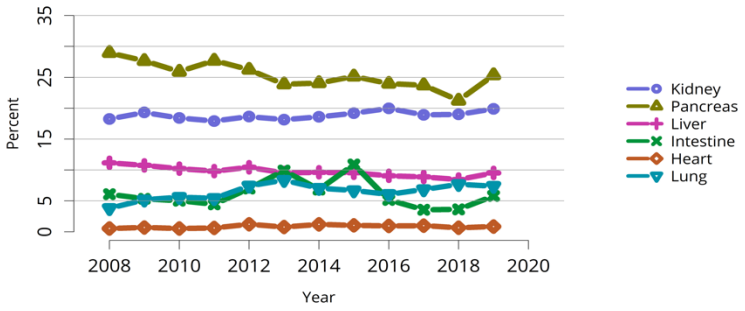
Organ Discards

The RFI indicates that CMS is interested in ways information on organ discard rates and organ acceptance practices can become more available and whether CMS should track and evaluate this information more closely and consider it for recertification purposes. In particular, CMS expresses concern that research indicates that many of the organs that are not accepted by transplant programs are later transplanted successfully at other transplant centers or are discarded despite having similar or "better" quality characteristics than organs that are successfully transplanted.

Organ Discards: The Problem in Context

In light of growing waiting lists, ASTS agrees the rate of organ discard is troublesome and that more should be done by the transplant community to ensure increased utilization of all potentially usable organs. The percent of organs recovered for transplantation that are not transplanted is particularly worrisome in the case of kidneys, with the kidney discard percentage hovering at about 20%.

Figure 9. Rates of organs recovered for transplant and not transplanted



OPTN/SRTR 2019 Annual Data Report

At the same time, It is important to keep in mind both that significant progress has been made in organ utilization and that there are limits to the extent to which organ discards can be eliminated. That substantial progress has been made is evident:

- The number of deceased organ donors and deceased-donor organ transplants performed in 2020 and 2021 in the United States reached all-time highs.[5]

- Transplant programs have already significantly increased utilization of organs at risk of discard. For example, based on our analysis of USRDS data, from 2014 to 2020, the rate of increase in the recovery and utilization of high KDPI kidneys (the overwhelming majority of discarded kidneys) exceeded the rate of increase in the recovery and utilization of kidneys with lower KPDI.

- Particular progress has been made in the transplantation of organs at risk of discard because of viral infections such as HCV+,[6] HIV+,[7] and COVID-19+ organs.[8]

- As noted in the RFI, transplant programs have managed to increase the number of donations after circulatory death and increase the utilization of all organs from these higher risk donors.

Despite this progress, there are several significant limitations on the degree to which organ discards can or should be reduced or eliminated. The raison d'être of OPOs and transplant programs dictate their slightly different approaches to high risk organs. The OPOs' mission is to maximize procurement of potentially transplantable organs, while transplant programs are tasked with critical, life or death decisions regarding the actual suitability of those organs for uniquely individual potential candidates. OPOs being aggressive at recovering organs from all potentially suitable donors (i.e. casting a large net), will increase organ transplant but will naturally incur higher discard rates; the greater number of transplants is the relevant metric, not the number of discards. The decision to transplant a particular organ into a particular patient is a highly complex experience and data-based multivariate analyses performed by transplant professionals evaluating an organ have real life or death consequences for the potential recipients. Transplant programs are cognizant of the huge cost of transplanting an organ that fails to work adequately (morbidity and mortality for that recipient, costs to payers, and further strain on the organ supply as that recipient then re-enters the candidate pool). Therefore, to at least some extent, some organ discard is a predictable and an unsurprising consequence of the different roles played by OPOs and transplant programs.

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[5] https://unos.org/data/transplant-trends/.

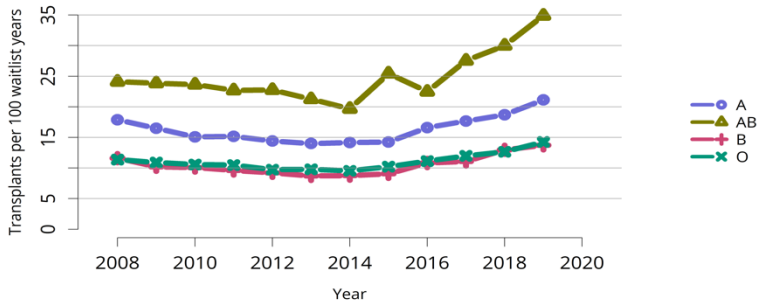
[6] Due to progress made in the research and evolution of new treatment of HCV and to the dedication of transplant researchers, the proportion of recovered but discarded HCV-positive kidneys continued to decline sharply starting in 2014; notably, in 2019, HCV-antibody-positive kidneys were discarded at nearly the same rates as HCV-antibody-negative kidneys. 2019 OPTN/SRTR Annual Data Report

[7] Nambiar PH, Doby B, Tobian AAR, et al. "Increasing the Donor Pool: Organ Transplantation with Donors with HIV to Recipients with HIV", *Annu Rev Med* 2021 Jan 27;72:107-108. doi:10.1146/annurev-med-060419-122327.

[8] Koval CE, Poggio ED, Lin Y, et al. "Early success transplanting kidneys from donors with new SARS-Cov-2 RNA positivity: A report of 10 cases". *Am J Transplant* 2021; 21:3743-3749.

Lessons can be learned from analyzing the jump in the kidney discard rate from 5.1% in 1988 to 19.2% by 2009 (approximately where it is today).[9] One study showed that at least 80% of the discard rate rise can be explained by the recovery of kidneys from an expanding donor pool of marginal organs, indicating that the majority of the rise in discards can only be mitigated through procurement innovation, organ preservation, and transplant research. The 2019/2020 Annual Data Report provides additional insight about potential limitations on the extent to which kidney discards can be reduced or eliminated:

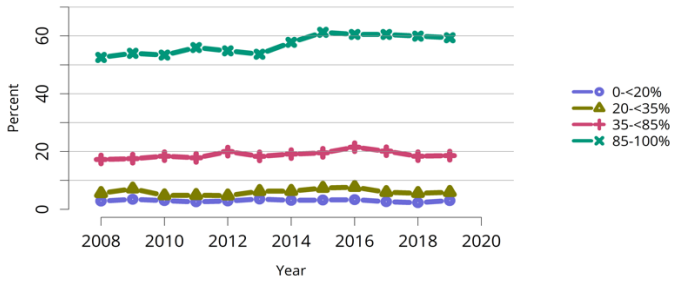
Figure 19. Deceased donor kidney transplant rates among adult waitlist candidates by blood type



OPTN/SRTR 2019 Annual Data Report

- Less than half of candidates aged 50-64 and less than two-thirds of candidates aged ≥65 years are willing to accept high KDPI kidneys (KDPI >85%), which constitute the majority of kidneys recovered but not transplanted.

Figure 60. Rates of kidneys recovered for transplant and not transplanted by KDPI



OPTN/SRTR 2019 Annual Data Report

- Rates of non-utilization are highest for kidneys recovered from donors ≥55 years old and those with diabetes, hypertension, or high BMI. In light of ongoing demographic trends in the broader

[9] https://journals.lww.com/transplantjournal/Fulltext/2017/03000/Diagnosing_the_Decades_Long_Rise_in_the_Deceased.23.aspx.

population, it may be anticipated that the proportion of kidneys that fall within these hard-to-place categories will continue to increase.

- The average Kidney Donor Risk Index (KDRI) of discarded kidneys continued to rise in 2019, suggesting that high-quality kidneys generally were not being discarded.

All this having been said, we believe that several systemic changes can and should be made to make better use of the organs procured for transplantation.

Kidneys Declined and Transplanted Elsewhere

In discussing the organ discard problem, the RFI notes that many organs are transplanted successfully after having been declined by one or more transplant program(s). The implication appears to be that any transplant program that declines an organ that is subsequently transplanted has made an inappropriate clinical judgment. But the calculus is not that simple. A determination to accept or decline an organ offer for a particular patient necessarily involves complex clinical decision-making that must take into account a multitude of factors.

Many factors (donor quality, immunologic match, transportation logistics, recipient characteristics/anatomy) impact organ acceptance. Characteristics of an organ that may impact the decision include: size of the kidney, vascular anomalies/vascular disease, biopsy findings, pump flow characteristics, donor cause of death, donor location, and anticipated cold ischemic time, warm ischemic time (for DCD donors), donor comorbidities (diabetes, hypertension, immunologic disease, infection, cancer, drug use, environmental/toxic exposures, cause of death, down-time prior to EMS, donor size, evidence of preexisting, chronic donor organ dysfunction), procurement findings, procurement injury, and the condition of the potential recipient (including but not limited to sensitization, peripheral vascular disease, temporary illness at the time of offer), refusal to accept a difficult to place organ or inability to travel to the transplant center at the time of offer, and any change since last medical follow-up that makes transplant risk prohibitive, examples include acute coronary syndrome, COVID or other acute illness, diagnosis of cancer, heart disease, cognitive decline, deterioration of other organ function that provides additional comorbidity, weight gain or loss, change in social support, and changes in insurance coverage and thus access to necessary immune-suppression treatment or post-transplant care. Further complicating the decision-making process is a wide range of logistical factors (such as the location of the organ, the availability of perfusion technology and transport issues which include the availability of airplanes, weather, suitability of available planes for perfusion equipment; the distance from the airport to the center; and the potential for missed connections or airtime that could necessitate a change of pilots). How these multitudinous factors are considered and weighted varies considerably based on the patient condition and chances of survival. Decisions necessarily vary not only from institution to institution, but from surgeon to surgeon. In fact, the decision to accept or decline an organ offer is by far the most difficult decision for transplant teams and, in some centers, such decisions are reserved for the most experienced surgeons.

Organ offers are made to a transplant program for a *particular* waitlisted patient on the match run, who is identified and prioritized based on OPTN allocation policy. Transplant Center A may decline an organ offer for Potential Recipient A, for an organ subsequently accepted by Transplant Center B for Potential Recipient B, but that does not mean that either Transplant Center A or Transplant Center B made the "wrong" decision. Not all potential recipients, not all organs, and not all transplant programs are created

equal. An organ rejected for Potential Recipient A may be perfectly acceptable for Potential Recipient B. Any physiologic aberration in the offered organ could impact the chances of survival of patient A, who by definition has a higher acuity than patient B. Other factors can also impact the decision; while it might be irresponsible for a small relatively new transplant program with limited resources or no experience in transplanting a particular type of difficult to place organ, to accept such an organ; it might be quite appropriate for Transplant Center B, a center with considerable resources and experience in that area, to do so. Likewise, using a difficult to place older donor organ in a young patient who is first on the list is not optimal when this could be used in an older patient who is more likely to benefit from an organ with a short-expected survival. Nor is the fact that an organ that is declined by some programs and transplanted by another necessarily a testimony to the good judgment of the transplant program that performed the transplantation: The clinical appropriateness of the transplant cannot be determined unless and until the longer term outcome is known. We urge caution in attempting to assess transplant program performance based solely on the number of organs it declines that are subsequently transplanted elsewhere while ignoring the complexities outlined above.

Systemic Factors

A number or systemic factors should be taken into consideration in assessing public policy options for addressing organ discards:

- As emphasized in other sections of these comments, one of the most significant factors contributing to organ discards is the substantial disincentive to transplantation created by current OPTN/MPSC transplant center performance metrics and the SRTR star ratings.

- "Official" organ acceptance rates do not provide an accurate way to compare transplant programs' willingness to accept organs at risk of discard. In order to ensure that precious time is not wasted offering organs to transplant programs that are highly unlikely to accept them, each transplant program specifies the criteria that must be met for the program to consider that organ for transplantation. Organs that do not meet those criteria are not offered to the program, saving time and increasing the likelihood of organ placement. This is a critical component of the system and functions to maximize the likelihood of organ placement systemwide. However, because transplant program organ acceptance criteria differ, cross-program comparison of organ acceptance rates are misleading: A transplant program with narrow organ acceptance criteria may have a high "acceptance rate" but may be considerably more selective than a program that is willing to consider a broader range of difficult to place organs but that has a substantially lower "acceptance rate." Therefore, reliance on existing data methodologies to track acceptance rates would be inappropriate and comparisons of organ acceptance rates across transplant programs is not advisable.

  Current offer acceptance rate statistics are not based on a tabulation of the number of organs that a transplant program accepts and the number it declines and for this reason can be deceptive. If a transplant program accepts a single organ, then that counts for OPTN reporting purposes as a single acceptance. However, if a transplant program declines a single organ for all of its patients on a match run, that decision "counts" as a separate "declined organ" for each of those patients. Furthermore, if a transplant program believes that an organ is appropriate for transplantation, but only for a particular waitlisted patient, that program may need to decline the organ multiple times until the organ is offered to that patient. Given this type of

"scorekeeping," a large transplant program's organ acceptance statistics can begin to look extraordinarily conservative very quickly. For example, the most recent PSR report for a large kidney transplant program in the Northeast USA showed that they had received 25,183 kidney offers and accepted 186. This type of statistic, if not properly interpreted, could be misread by the regulators and the public as evidence of a low transplantation rate when this program is one of the largest in its region.

- Because new organ allocation policies that have been adopted relatively recently (e.g. March 15, 2021 for the new kidney allocation policy) require organs to be offered much more broadly, they have added complexity to organ distribution logistics particularly as the distribution circles widen. For this reason, we urge focus and centralized efforts to enhance efficiency of organ transportation logistics in order to minimize cold ischemia time that is expected to increase organ acceptances. Expanded geography has also disrupted historical working relationships between OPOs and their area transplant programs. For these reasons, efforts to reduce organ discards by focusing primarily on improving communication between a transplant program and its local OPO are unlikely to succeed.[10]

- The inclusion of individualized organ acceptance criteria for potential recipients in the organ matching software may significantly increase the efficiency of the system and expedite the placement of transplantable organs.

  Minimizing organ wastage is likely to require modification of organ allocation policies for hard to place organs. For example, transplant programs' acceptance of these organs likely would increase significantly if allocation rules were altered such that, after a difficult to place organ is offered to a specified number of waitlisted patients in priority order, the organ could be accepted for any clinically appropriate patient on the match run, regardless of priority order.

Our Recommendations

With these considerations in mind, we turn to the questions posed in the RFI. In our view, the first step is to accurately diagnose which features of the current system are the primary contributors to organ wastage.

RECOMMENDATION: We believe that, as a first step, a comprehensive study is needed to obtain greater understanding of why and which organs are being declined.

Such a study should include both a qualitative component that engages the transplant community in discussions regarding their organ acceptance practices as well as a quantitative analysis that takes into account the full range of systemic factors potentially impacting organ acceptance, including the efficiency of the current matching system, implications of current allocation policies for hard to place organs, travel and other logistics, and other factors. Data collected by the OPTN using the new organ refusal coding system should be analyzed closely to refine efforts to maximize utilization of useable organs.

[10] https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf.

RECOMMENDATION: ASTS supports the dissemination of actionable data regarding organs declined and transplanted elsewhere. We also support the addition of a requirement in the Interpretive Guidelines that would encourage transplant programs to review this data as part of the QAPI process.

However, we do not believe that CMS should establish a minimum acceptable organ acceptance rate as a condition of certification or recertification, or that a transplant program otherwise should be placed under pressure to modify clinical judgments regarding the suitability of organs for transplantation in order to obtain or maintain Medicare certification. *There are no prior examples for forcing alteration of clinical practice for Medicare certification reasons and it is a very dangerous precedence to regulate clinical judgment.*

For the reasons discussed above, we believe that much can be done to reduce organ discards by reforming a number of systemic features of the current regulatory system.

RECOMMENDATION: We encourage CMS and the OPTN to work with the transplant community to establish separate allocation policies, transplant outcome measures, and other process enhancements to encourage acceptance of difficult to place organs.

We also believe that much can be gained from non-regulatory approaches to encouraging increased utilization of difficult to place organs.

RECOMMENDATION: We encourage CMS and other agencies to consider non-regulatory approaches that are likely to be effective to maximize utilization of hard to place organs. Examples include:

- **Broad dissemination of best practices for the transplantation of difficult to place organs through the Kidney Transplant Collaborative and educational programs sponsored by ASTS and others;**

- **A modification of the inpatient prospective payment system that adjusts DRG payments to account for the additional costs involved in these transplants;[11]**

- **The dedication of research resources including transplant specific NIH funding should be allocated to investigate strategies to improve the functional assessment, reverse acute injury and improve outcomes of difficult to place organs.[12] Examples include: research into organ viability and**

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[11] Sameera Senanayake, Nicholas Graves, Helen Healy, Keshwar Baboolal, Adrian Barnett, Matthew P. Sypek, Sanjeewa Kularatna, *Donor Kidney Quality and Transplant Outcome: An Economic Evaluation of Contemporary Practice,* Value in Health, Volume 23, Issue 12, 2020, Pages 1561-1569, ISSN 1098-3015, *https://www.valueinhealthjournal.com/article/S1098-3015(20)32250-6/fulltext?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS1098301520322506%3Fshowall%3Dtrue.*

David Axelrod, Mark Schnitzler, Huiling Xiao, William Irish, et.al, *An economic assessment of contemporary kidney transplant practice*, AJT, 28 January, 2018, https://onlinelibrary.wiley.com/doi/epdf/10.1111/ajt.14702.

[12] Resch Thomas, Cardini Benno, Oberhuber Rupert, Weissenbacher Annemarie, Dumfarth Julia, Krapf Christoph, Boesmueller Claudia, Oefner Dietmar, Grimm Michael, Schneeberger Sefan, Transplanting Marginal Organs in the Era of Modern Machine Perfusion and Advanced Organ Monitoring, Frontiers in Immunology, Volume 11, Year

rejuvenation, and ex-vivo perfusion, so that organ acceptance of difficult to place organs is driven by sound scientific practices. Within the broad category of organs at risk of discard, some likely could be transplanted with acceptable results, but the current state of the art and the parameters used to evaluate these organs cannot identify these organs. DCD organ discards are being gradually reduced by utilization of perfusion in the donor and in the ex-vivo setting. Supporting this research and expanding it through the NIH and/or AHRQ could identify markers for viability and or better techniques to increase organ utilization yield and hopefully limit the regulatory only solutions for this problem.

2020, DOI 10.3389/fimmu.2020.00631, ISSN=1664-3224,
https://www.frontiersin.org/article/10.3389/fimmu.2020.00631.

BETTER PATIENT CARE AND TRANSPARENCY

Transplant Quality

The RFI solicits data on whether transplant programs adequately protect the health and safety of living donors and transplant patients and on whether there are improvements needed to the transplant program Conditions of Participation to incentivize and improve quality of care. We hope that the following data is helpful to CMS in considering these issues.

Quality of Care: Transplant Recipients

There are numerous publications demonstrating the increased life expectancy, overall health, and improved quality of life from transplant compared to dialysis for renal replacement therapy. In addition, transplant outcomes continue to improve as demonstrated by the most recent data from the US Renal Dialysis System (2020),[13] which is primarily a non-transplant data system, where renal transplant graft and patient survival has continued to improve (Figures 6.16, 6.17) despite the increasing age and illness of transplant recipients (Figure 6.10).

Transplant dramatically improves patient survival with cardiovascular disease as compared to dialysis (Figure 8.2). All-cause adjusted mortality (Figure 5.1) was 160.8 per thousand patient years on dialysis compared to 48.9 after transplant. All measurements of patient survival and costs for renal replacement therapy strongly demonstrate the benefit of transplant over dialysis. Results are similar for other types of organ transplantation.[14] Federal regulations and reimbursement should be adjusted to strongly support increasing transplantation in the U.S. for both patient outcome and cost concerns.

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[13] https://adr.usrds.org/2020.

[14] Northup PG, Abecassis MM, Englesbe MJ, Emond JC, Lee VD, Stukenborg GJ, Tong L, Berg CL; Adult-to-Adult Living Donor Liver Transplantation Cohort Study Group. Addition of adult-to-adult living donation to liver transplant programs improves survival but at an increased cost. Liver Transpl. 2009 Feb;15(2):148-62. doi: 10.1002/lt.21671. PMID: 19177435; PMCID: PMC3222562.

Washburn WK, Pollock BH, Nichols L, Speeg KV, Halff G. Impact of recipient MELD score on resource utilization. *Am J Transplant*. 2006; 6(10): 2449- 2454. Wiley Online LibraryCASPubMedWeb of Science®Google Scholar

Axelrod DA, Koffron AJ, Baker T, Al-Saden P, Dixler I, McNatt G. The economic impact of MELD on liver transplant centers. *Am J Transplant*. 2005; 5(9): 2297- 2301. Wiley Online LibraryPubMedWeb of Science®Google Scholar

Buchanan P, Dzebisashvili N, Lentine KL, Axelrod DA, Schnitzler MA, Salvalaggio PR. Liver transplantation cost in the model for end-stage liver disease era: looking beyond the transplant admission. *Liver Transpl*. 2009; 15(10): 1270- 1277. Wiley Online LibraryCASPubMedWeb of Science®Google Scholar

Salvalaggio PR, Dzebisashvili N, MacLeod KE, et al. The interaction among donor characteristics, severity of liver disease, and the cost of liver transplantation. *Liver Transpl*. 2011; 17(3): 233- 242. Wiley Online LibraryPubMedWeb of Science®Google Scholar

In short, the quality of transplantation, at least as measured in terms of patient outcomes, is truly impressive: The larger issue is how to make transplantation more accessible and its availability more equitable while maintaining high quality.

Quality of Care: Living Donors

The data also suggests that transplant programs adequately protect the health and safety of living donors. To donate a kidney does not seem to constitute any long-term risk.[15] The risk of death for living kidney donors within 30 days of surgery is very low. Between Oct. 25, 1999, and Jan. 23 2015, five living kidney donors have died in the United States one to two years after donation from causes determined to be medical in nature, according to OPTN.[16] Three of these deaths were related to a specific type of surgical clip that is now not being used in living donation.[17] Living donor liver transplant (LDLT) accounts for a small volume of the transplants in the USA, and donor risk appears to be low overall, with a favorable long-term quality of life. The latest trend has been a gradual shift from right-lobe grafts to left-lobe grafts to reduce donor risk, provided that the left lobe can provide adequate liver volume for the recipient.[18]

With absolute numbers of adverse living donor events remaining so low, safety in living donation has been emphasized by programs, and there is little variation in living donor outcomes between them.[19] This climate of safety has allowed for the responsible but much needed expansion of living donation in the last decade. This expansion has arisen through the generosity of individuals who come forward to be evaluated, and through the thorough evaluation and surgical care of living donor candidates. This expansion has led to innovations including an increased use of local and national paired donor

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Axelrod DA, Dzebisashvili N, Lentine K, et al. Assessing variation in the costs of care among patients awaiting liver transplantation. *Am J Transplant*. 2014; 14(1): 70- 78. Wiley Online LibraryCASPubMedWeb of Science®Google Scholar.

Dutkowski P, Oberkofler CE, Bechir M, et al. The model for end-stage liver disease allocation system for liver transplantation saves lives, but increases morbidity and cost: a prospective outcome analysis. *Liver Transpl*. 2011; 17(6): 674- 684. Wiley Online LibraryPubMedWeb of Science®Google Scholar.

[15] Fehrman-Ekholm I, Elinder CG, Stenbeck M, Tydén G, Groth CG. Kidney donors live longer. Transplantation. 1997 Oct 15;64(7):976-8. doi: 10.1097/00007890-199710150-00007. PMID: 9381544.

[16] https://www.healio.com/news/nephrology/20180227/ucsf-medical-center-suspends-living-kidney-donor-p.

[17] https://www.cnn.com/2012/06/20/health/kidney-clips/index.html.

[18] Kim PT, Testa G. Living donor liver transplantation in the USA. *Hepatobiliary Surg Nutr*. 2016;5(2):133-140. doi:10.3978/j.issn.2304-3881.2015.06.01.

[19] See: https://adr.usrds.org/2020/end-stage-renal-disease/6-transplantation and SRTR Kidney and Liver reports: https://onlinelibrary.wiley.com/doi/10.1111/ajt.16502 and https://onlinelibrary.wiley.com/doi/10.1111/ajt.16494.

exchange,[20] a significant increase in anonymous non-directed living kidney and livers donors, and other innovative programs.

RECOMMENDATION: We support efforts to make transplantation more accessible and its availability more equitable while maintaining high quality standards through the use of the QAPI process to address access issues as well as issues related to clinical improvement.

Optimal Patient Care: Pre-emptive Transplantation and Living Donation Patient Access

The RFI states that CMS is actively working to identify and address disparities and inequities across dialysis and transplant programs. We believe that the current system as it relates to the start of Medicare coverage for dialysis patients has an unintended consequence of promoting a dialysis first clinical pathway, particularly for patients relying solely on Medicare coverage to gain access to transplantation. We are very encouraged that CMS is considering remedies for these situations. Unfortunately, the rate of pre-emptive transplantation within the first year of starting dialysis and the utilization of living donation for these transplants remain unacceptably low. Most patients with chronic kidney disease are diagnosed as their renal function is declining and having appropriate coverage at this time could promote pre-emptive referral and living donor transplants. A major disincentive to the underserved populations in the current environment is also the lack of resources for patients to undergo pre-transplant evaluation with its associated medical and non-medical costs.

Recommendation:

- **We encourage CMS to redesign ESRD coverage to include low eGFR patients starting a transplant work-up so that low resourced patients can be included in coverage and can be part of pre-emptive living donor transplants.**

- **We urge CMS to include a requirement that transplant providers by responsible for pre-ESRD education.**

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[20] Montgomery RA, Zachary AA, Ratner LE, Segev DL, Hiller JM, Houp J, Cooper M, Kavoussi L, Jarrett T, Burdick J, Maley WR, Melancon JK, Kozlowski T, Simpkins CE, Phillips M, Desai A, Collins V, Reeb B, Kraus E, Rabb H, Leffell MS, Warren DS. Clinical results from transplanting incompatible live kidney donor/recipient pairs using kidney paired donation. JAMA. 2005 Oct 5;294(13):1655-63. doi: 10.1001/jama.294.13.1655. PMID: 16204665.

Raza MH, Kaur N, Sher L, Genyk Y, Emamaullee J. Anonymous Nondirected Living Liver Donation in the United States. Transplant Direct. 2021 Dec 23;8(1):e1275. doi: 10.1097/TXD.0000000000001275. PMID: 34966843; PMCID: PMC8710328.

Expanding living donor liver transplantation: Report of first US living donor liver transplant chain. Braun HJ, Torres AM, Louie F, Weinberg SD, Kang SM, Ascher NL, Roberts JP.Am J Transplant. 2021 Apr;21(4):1633-1636. doi: 10.1111/ajt.16396. Epub 2020 Dec 8.PMID: 33171017

Osbun N, Thomas AG, Ronin M, Cooper M, Flechner SM, Segev DL, Veale JL. The benefit to waitlist patients in a national paired kidney exchange program: Exploring characteristics of chain end living donor transplants. Am J Transplant. 2022 Jan;22(1):113-121. doi: 10.1111/ajt.16749. Epub 2021 Jul 17. PMID: 34212501; PMCID: PMC8720056.

- **We believe that it is important to consider a financial assistance program similar to NLDAC for low resourced patients to help defray out-of-pocket expenses and other financial disincentives to completing work-ups and obtaining a living donor transplant.**

- **CMS should consider removing disincentives to living donation.**
    - **Extend the period of coverage for organ donation related complications.**
    - **Explore funding demonstration projects aimed at increasing altruistic donation and providing long-term protection for the health of altruistic donors.**
    - **Fund a national education campaign promoting altruistic and related living donations.**

Conditions of Participation (CoPs)

On the whole, the current process requirements in the transplant program CoPs have contributed significantly to quality improvement. Other than the elimination of duplication, we do not believe that significant substantive changes to the transplant program CoP "process requirements" are necessary or warranted, nor do we believe that the CoPs create significant barriers to the establishment of new transplant programs.

Over the years, we have appreciated the opportunity to partner with CMS in resolving survey-related questions as they have arisen from time to time and in addressing ambiguities in the Interpretive Guidelines. It has been our experience that those issues that have arisen in this area relate to differences in interpretation among state survey agencies, leading to a lack of uniformity across the country, and to surveyors lack of experience in the area of transplantation, with its unique and complex processes of care.

RECOMMENDATION: We look forward to engaging with CMS to resolve certain 2019 revisions to the Interpretive Guidelines, which remain subject to considerable confusion. In order to minimize variation in survey practices among state agencies, we also urge CMS to consider the centralizing survey authority by contracting with a single organization experienced in the survey of transplant centers to conduct surveys throughout the country.

We believe that CMS could play a significant positive role by utilizing CoPs/CfCs to "link" the disparate providers in the transplant ecosystem. The potential for CoPs/CfCs to reinforce communication among transplant providers is especially critical when it comes to patient education.

RECOMMENDATION: We request that CoPs/CfCs be modified in order to ensure that transplant programs play the central role in patient education related to both living and deceased donor transplantation. Transplant programs are in the best position to provide patient-centric educational programs and materials, including information regarding the availability of funding for living donor expenses through the National Living Donor Assistance Program (NLDAC) and dialysis facilities should be required to engage with transplant programs for the provision of accurate and timely patient education.

Transplant Recipient Patient Rights (Increasing Transparency)

The RFI solicits comments on the degree of transparency that should be required of programs to ensure that patients on the waitlist receive the information they need to make decisions about their care and to ensure that transplant programs and surgeons are accountable and transparent in their decisions to decline organs.

While we share CMS' interest in transparency, we would also like to remind CMS that more data is publicly available regarding essentially every aspect of transplant program operations than for providers in virtually any other field of medicine. This includes detailed center-level data on waitlist composition (including demographic data – age, race, ethnicity, gender), blood type, the percentage of waitlisted patients previously transplanted, primary disease, and CPRA), as well as detailed data on each program's organ acceptance practices.

The publicly available data regarding center specific organ acceptance practices illustrates the impracticality of a system under which each waitlisted patient is informed whenever a transplant program receives an organ offer for that patient. SRTR data indicates that, during the period from July 1, 2020, through June 30, 2021—a period when transplant program operations were significantly impacted by COVID-19—2,114,234 deceased donor kidney offers were made. The number of deceased donor kidney offers received by the top five high volume kidney transplant programs range from 10,527 to 17,715—**an average of 29 to 49 per day.** It would clearly be impractical for each organ offer to be transmitted to and discussed with the potentially impacted waitlisted patient.

Also, it is not clear to us what such a requirement would accomplish—other than to increase waitlisted patients' anxiety and frustration. As discussed above, the decision about whether or not to accept an organ offer is quintessentially a clinical judgement—and an extremely complex one at that. Patients opinion and preferences are obtained at the time of listing, but decisions regarding whether or not to accept an organ for transplantation simply cannot be made by patients. Nor is it at all clear what would or should happen if a patient who is desperate for a transplant were to disagree with the decision to decline an organ. While we believe that waitlisted patients can and should be provided with accurate, comprehensive periodic reports of their transplantation prospects, the suggestion that each organ offer be shared with the potentially affected waitlisted patient(s) is entirely impracticable and is likely to result in a host of unanticipated consequences.

RECOMMENDATION: While ASTS believes that patient involvement is necessary in clinical decision making in the elective situation, we strongly oppose any regulatory provision that would require a transplant program to share all organ offers with potentially impacted waitlisted patients. Because any such requirement would be impracticable, we believe that a transplant program's organ acceptance practices should be discussed thoroughly with patients prior to listing as part of the transplant center pre-transplant education.

RECOMMENDATION: ASTS supports increasing transparency to provide meaningful data to patients on their waitlist status, both at the time of listing and periodically throughout the time they are waitlisted.

IMPROVING EQUITY IN ORGAN DONATION AND TRANSPLANTATION

Equity in Organ Transplantation and Organ Donation (Disparities)

The transplant community (and transplant centers in particular) have been proactively and aggressively working to increase access to transplantation for the historically underserved, highly immunologically sensitized, economically disadvantaged, and people of color. Examples include development and implementation of the Kidney Allocation System (KAS) and eliminating DSA and Region as units of allocation in favor of Acuity Circles. Ongoing work on improving the efficiency of organ allocation via improvements to organ offer filters and match run rules are further examples. Transplant Centers have been key drivers of these recent, present, and future changes.

Throughout, ASTS has been supportive of, and a critical driver of, these changes to increase equity and access.

- The ASTS *Statement of Principles* specifically outlines our commitment to encouraging transplant professionals to continuously work to identify and eliminate Transplant Center processes that may differently impact transplant access and outcomes by race, gender, gender identification, religion, ethnic background, disability, or other social factors.

- ASTS also supports the effort to limit the consideration of non-clinical factors in waitlist practices (comments submitted supporting the OPTN White Paper ***General Considerations in Assessment for Transplant Candidacy*** (see ASTS Comment #9) which dissuades consideration of socioeconomic factors in waitlist decisions.

- ASTS has adopted a policy statement intended to encourage transplant programs to make transplantation more accessible to the physically and mentally disabled (see ASTS Statement Concerning Eligibility for Solid Organ Transplant Candidacy)

- To put these principals into action, ASTS has a long-standing Diversity, Equity, and Inclusion Committee devoted to addressing these issues.

- In 2020, ASTS also 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 will involve 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.

We recognize that additional steps that are clearly needed. With respect to clear disparities in donation, ASTS has responded to inquiries from Congress and from AHRQ (RFI regarding Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery). In its responses, ASTS supports elimination of the 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.[21]

RECOMMENDATION: We encourage CMS to work with the chronic kidney disease community to adopt a quality measure that discourages the use of race correction in eGFR calculations and to support educational outreach regarding this issue to the primary care and nephrology communities who refer patients for transplant evaluation. (See: ASTS Statement of Principles)

On the other hand, we need to acknowledge at least some progress in addressing racial disparities in access to transplantation. For example, to address systemic delays in the referral of minorities on dialysis for transplant evaluation, a modification was made in the kidney allocation policy that counts time on dialysis as if it were time on the waitlist. There is evidence that this change has ameliorated some of the racial disparities in the system.[22] (See UNOS Report)

In addition, we believe that there are ways that transplant programs and OPOs could or should consider social determinants of health in their policies. Studies have demonstrated that social determinants of health (SDH) matter, and there are a number of examples in which SRTR data were linked to other national data sets that have been deemed good surrogates of SDH. For example, SDH impact kidney donation rate per 100 eligible deaths[23] and disparities are particularly glaring for living donor organ transplants.[24] There is evidence that patient navigator programs may be of some assistance in mitigating some of these disparities.[25]

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[21] Organ donation in diverse communities: The pitfalls of race correction Malay B. Shah, Lee S. Cummings, Stephen H. Gray, Andre A. S. Dick. First published: 26 May 2021.

[22] We note that references 6, 7, 8, 9, 10 in the RFI were published before these changes in allocation policy were made.

[23] Reed RD, Shelton BA, Mustian MN, MacLennan PA, Sawinski D, Locke JE. Transplantation. 2020 Feb;104(2):421-427. doi: 10.1097/TP.0000000000002831.PMID: 32004235 Geographic Differences in Population Health and Expected Organ Supply in the Gulf Coast Region of the United States Compared to Non-Gulf States.

[24] Reed RD, Sawinski D, Shelton BA, MacLennan PA, Hanaway M, Kumar V, Long D, Gaston RS, Kilgore ML, Julian BA, Lewis CE, Locke JE**.** Transplantation. 2018 Dec;102(12):2080-2087. doi: 10.1097/TP.0000000000002286.PMID: 29787519 Population Health, Ethnicity, and Rate of Living Donor Kidney Transplantation.

Killian AC, Shelton B, MacLennan P, McLeod MC, Carter A, Reed R, Qu H, Orandi B, Kumar V, Sawinski D, Locke JE.JAMA Surg. 2021 Dec 1;156(12):1120-1129. doi: 10.1001/jamasurg.2021.4410.PMID: 34524392 Evaluation of Community-Level Vulnerability and Racial Disparities in Living Donor Kidney Transplant.

[25] Impact of Social Vulnerability on Access to Educational Programming Designed to Enhance Living Donation. Carter AJ, Reed RD, Kale AC, Qu H, Kumar V, Hanaway MJ, Cannon RM, **Locke JE.** Prog Transplant. 2021 Dec;31(4):305-313. doi: 10.1177/15269248211046014. Epub 2021 Oct 29.PMID: 34713750.

Self-advocacy is associated with lower likelihood of living donor kidney transplantation.
Killian AC, Reed RD, Carter A, McLeod MC, Shelton BA, Kumar V, Qu H, MacLennan PA, Orandi BJ, Cannon RM, Anderson D, Hanaway MJ, **Locke JE.** Am J Surg. 2021 Jul;222(1):36-41. doi: 10.1016/j.amjsurg.2020.12.035. Epub 2020 Dec 24.PMID: 33413873.

RECOMMENDATION: ASTS believes that patient education is critical if disparities are to be reduced. By placing transplant programs front and center in the provision of transplant-related education, especially at dialysis centers, we anticipate that increased awareness of the benefits of transplantation will, over time, increase the number of transplant evaluations performed for minorities and the medically underserved.

Organ Acquisition and Organ Recovery Centers

The RFI indicates that CMS is interested in learning about the potential benefits and drawbacks of organ recovery centers (ORCs) in greater detail and determining whether it would be appropriate or beneficial to establish specific health and safety requirements that would apply to these facilities.

While the facilities provided by ORCs differ, in general ORCs provide standardized and specialized testing for all potential donors. Many ORCs possess the ability to do CT scans, echocardiograms, fluoroscopy, and even cardiac catherization, as well as specialized testing that is not typically available in smaller donor hospitals, such as CT volumetry to facilitate split liver or lung donation. Some ORCs have the capability to perform infection testing on site, while others ship out the donor testing samples from a centralized location.

ASTS believes that ORCs can improve organ donation significantly, with increased safety, efficiency and more cost-effectively:

- By transferring potential organ donors to a centralized ORC, an OPO is able to provide standardized donor management and testing, allow for faster testing and procurement, with fewer staff.

- Because of their centralized location (usually closer to or at a transplant center), organ procurements can be scheduled more easily, allowing for appropriate time coordination for transplant centers, so as to minimize ischemic time and improve organ function.

The Living Donor Navigator Program Provides Support Tools for Caregivers.
Reed RD, Killian AC, Mustian MN, Hendricks DH, Baldwin KN, Kumar V, Dionne-Odom JN, Saag K, Hites L, Ivankova NV, **Locke JE.** Prog Transplant. 2021 Mar;31(1):55-61. doi: 10.1177/1526924820978598. Epub 2020 Dec 23.PMID: 33353498.

A Qualitative Assessment of the Living Donor Navigator Program to Identify Core Competencies and Promising Practices for Implementation. Reed RD, Hites L, Mustian MN, Shelton BA, Hendricks D, Berry B, MacLennan PA, Blackburn J, Wingate MS, Yates C, Hannon L, Kilgore ML, Locke JE. Prog Transplant. 2020 Mar;30(1):29-37. doi: 10.1177/1526924819892919. Epub 2019 Dec 16.PMID: 31838948.

Enhanced Advocacy and Health Systems Training Through Patient Navigation Increases Access to Living-donor Kidney Transplantation. Locke JE, Reed RD, Kumar V, Berry B, Hendricks D, Carter A, Shelton BA, Mustian MN, MacLennan PA, Qu H, Hannon L, Yates C, Hanaway MJ. Transplantation. 2020 Jan;104(1):122-129. doi: 10.1097/TP.0000000000002732.PMID: 30946213.

- The use of ORCs is safer for transplant teams, who do not need to travel across long distances, oftentimes at night.

- ORCs are particularly efficient for procurement of organs at risk of discard, since ORCs allow more time for donor management and organ procurement, allow for some recovery in cases involving acute injury, facilitate faster access to perfusion, and provide more time for transplant centers to assess the organs prior to recovery.

- Emerging data suggests that expert handling of the deceased donor at an ORC also has the potential to significantly increase organ yield,[26] mitigating shortages for extrarenal organs.

- There does not appear to be any data that suggest or implies that the use of ORCs is disturbing for donor families or that it adversely impacts tissue recovery.

- Furthermore, ORCs have the potential to coordinate organ recoveries during safer hours increasing healthcare team and patient safety.

RECOMMENDATION: In light of the significant benefits of ORCs, ASTS supports resource allocation to increase organ procurement at ORCs and the expeditious formulation of standards for these entities by CMS and HRSA in collaboration with the transplant community.

Because of the need for full community involvement and interagency cooperation, it would appear unlikely that such standards can be adopted quickly enough to meet the pressing need for modernization of organ acquisition processes. In the interim, progress is continuing.

RECOMMENDATION: Pending the development of new ORC standards, we encourage CMS to work with ASTS and others in the transplant ecosystem to develop flexible guidelines for OPOs and transplant centers to work together to establish ORCs that are treated as services provided "under arrangements" with transplant programs, using the hospital's own facilities or facilities on the hospital campus.

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[26] M. Doyle, V. Subramanian, N. Vachharajani, K. Collins, J. Wellen, E. Stahlschmidt, D. Brockmeier, J. Coleman, D. Kappel, W. Chapman. 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 Sug. 2016; Apr; 222(4):591-600. 0.1016/j.jamcollsurg.2015.12.032. Epub 2016 Feb 29. Doi: See https://pubmed.ncbi.nlm.nih.gov/26947113/

P. Marsolais, E. Charbonney, K. Serri, A.-M. Lagace, F. Bernard, M. Albert. Invited Response to "Potential Disadvantages of Over Centralization of Organ Recovery Centers: Response to Marsolais et al." 27 June 2017/See: https://onlinelibrary.wiley.com/doi/10.1111/ajt.14411.

INCREASING ORGAN AVALABILITY AND TRANSPLANT RESEARCH

Increasing Donor Identification and the Number of Potential Organs Available for Transplantation

Expanding the cadaveric donor pool is one of the best and surest ways to increase organ availability and decrease the number of people on the waiting list. CMS has several regulations in place to encourage all hospitals to identify and refer organ donors to their respective OPOs. Despite this emphasis on donor identification, the growth of cadaveric donation has not matched the exponential growth on the waiting lists, and we believe that it is time for CMS to redesign its policies to encourage increased donor identification across the country. This issue has been absent in the national debate, and the fact that the limited number of organ donors contributes to lengthy debates about organ distribution has become obvious in the last few years. ASTS has proposed a model to HRSA to link donor hospitals into proposed incentivized payments for dialysis providers stemming from our belief that the cadaveric donor supply is a major system issue; driving increased death on the waiting list and utilization of less than ideal donors and increasing organ discards.

Recommendation:

- **We encourage CMS to require donation and death statistics to be part of every hospital benchmark and public dashboard similar to cancer data.**

- **CMS should incentivize donor identification in every hospital in the country by redesigning some of the pay for performance regulation to link Medicare payments to material success in implementation of donor identification, resuscitation, and consent for every potential donor.**

An existing example of stratification of baseline for performance comparison is CMS' Hospital Readmissions Reduction Program (HRRP), which now stratifies hospitals by dual-eligible patient population in order to not penalize hospitals that care for this population.

Donation after Cardiac Death

The ASTS appreciates CMS's interest in and recognition of the growth of Donation after Cardiac Death (DCD) organ recovery.[27] DCD donation has grown nationally in response to a series of significant changes in the characteristics of organ donors and technological improvements. For example:

- The ongoing opiate epidemic has resulted in a dramatic increase in the proportion of donors with anoxic brain injury. Many of these young donors will not progress to brain death (which results from herniation of the brain through the skull) but will remain neurologically devastated, and their families make the difficult decision to withdraw support and give the gift of life. Tragically, as the opiate epidemic appears to be continuing, it is likely that DCD donation from opiate-related deaths will represent an increasing proportion of the donor population.

[27] Israni AK, Zaun D, Rosendale JD, Schaffhausen C, McKinney W, Snyder JJ. OPTN/SRTR 2019 Annual Data Report: Deceased Organ Donors. *Am J Transplant*. Feb 2021;21 Suppl 2:521-558. doi:10.1111/ajt.16491.

- The COVID-19 epidemic has also contributed as centers have accepted organs from patients with severe COVID-19 who die from anoxic injury without herniation.[28]

- There has been a clinical shift in ICU management, to proactively address goals of care with families of individuals with devastating brain injuries. Studies have confirmed that withdrawal care proceed progression to brain death, and DCD donation provides an opportunity to utilize these organs.[29]

Equally important, outcomes from transplantation with DCD organs have dramatically improved, particularly for extra-renal transplant.[30] DCD kidney transplant results in near equivalent outcomes, although rates of delayed graft function are higher. DCD recovery of livers, pancreata, lungs, and hearts is increasingly common, particularly when accompanied by ex-vivo normothermic machine perfusion. Liver transplantation outcomes are now nearly equivalent for younger DCD and DBD liver transplant, provided the period from onset of the agonal period (low oxygen saturation and/or blood pressure) to cardiac arrest is brief (< 30 min). Early allograft dysfunction is reduced with machine perfusion and the long-term risk of ischemic cholangiopathy has diminished. Similarly, heart recovery after DCD donation is increasingly common with subsequent machine perfusion, organ assessment, and successful transplantation.[31] The increasing use of these organs is beneficial to CMS by increasing the organ supply and reducing the cost of donation for DCD kidney-only donors.

Transplantation is the only effective treatment for end-stage liver disease (ESLD) but is limited by insufficient access to suitable donor organs. In 2021, 1,117 patients in the U.S. died while awaiting liver transplantation and another 1,177 were removed from the waitlist due to being too sick to transplant. This effective 20% annual waitlist mortality has remained consistent despite the increasing number of U.S. liver transplants performed each year since 2012. Insufficient organ access results not only in the cost of human life, but also in financial costs to the health care system managing ESLD patients. In 2016 alone, the cost of ESLD care in the U.S. was estimated to approach $20 billion.

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[28] Kute VB, Fleetwood VA, Meshram HS, Guenette A, Lentine KL. Use of Organs from SARS-CoV-2 Infected Donors: Is It Safe? A Contemporary Review. Curr Transplant Rep. Oct 26 2021:1-12. doi:10.1007/s40472-021-00343-0.

[29] Robba C, Fossi F, Citerio G. Organ donation: from diagnosis to transplant. Curr Opin Anaesthesiol. Apr 2020;33(2):146-155. doi:10.1097/ACO.0000000000000826.

[30]Egan TM, Haithcock BE, Lobo J, et al. Donation after circulatory death donors in lung transplantation. J Thorac Dis. Nov 2021;13(11):6536-6549. doi:10.21037/jtd-2021-13.

Minambres E, Rubio JJ, Coll E, Dominguez-Gil B. Donation after circulatory death and its expansion in Spain. Curr Opin Organ Transplant. Feb 2018;23(1):120-129. doi:10.1097/MOT.0000000000000480.

Wu WK, Ziogas IA, Matsuoka LK, Izzy M, Alexopoulos SP. Applicability of the UK DCD risk score in the modern era of liver transplantation: A U.S. update. Clin Transplant. Dec 29 2021:e14579. doi:10.1111/ctr.14579.

[31] Madan S, Saeed O, Forest SJ, Goldstein DJ, Jorde UP, Patel SR. Feasibility and Potential Impact of Heart Transplantation From Adult Donors After Circulatory Death. J Am Coll Cardiol. Jan 18 2022;79(2):148-162. doi:10.1016/j.jacc.2021.10.042.

Significant barriers to DCD donation growth include operational, financial, and logistical issues:

- Operationally, OPOs face difficulties in identifying providers for end-of-life care at the time of donation.

- Financially, current cost allocation rules for OPOs decrease incentive to pursue extrarenal organs as cost for donors that do not progress are attributed to the organ acquisition costs.

- Logistically, OPOs face significant challenges with operating room availability at donor hospitals, especially since DCD procedures require the additional complexity of family presence during the period of withdrawal of life support.

Financial constraints also impact transplant programs that perform DCD procedures: DCD transplants require greater use of expensive biologic agents to prevent rejection while the graft is recovering, and these agents are not reimbursed separately but rather packaged into DRG payments, resulting in financial losses for the institution.

RECOMMENDATION: ASTS urges CMS to establish a work group to address financial barriers to DCD transplants arising from Organ Acquisition Cost (OAC) reporting and apportionment rules.

Development of New Treatments and Technologies

The preface to the RFI emphasizes the need to "Ensure that the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) policies appropriately incentivize the creation and use of future new treatments and technologies." Further, HHS seeks to "harmonize policies across the primary HHS agencies (CMS, the Health Resources and Services Administration (HRSA), and the Food and Drug Administration (FDA)) that are involved in regulating stakeholders in the transplant ecosystem so that our requirements are not duplicative, conflicting, or overly burdensome."

Historically, FDA approval and CMS coverage decision policy contribute to a lack of innovation in the development of immunosuppression treatments. Recently, the FDA declined an application to use an approved biomarker (iBox) to assess outcomes in clinical trials. Similarly, there has been reluctance to consider Real World Evidence in drug approval, despite transplant registry data which meets all FDA requirements (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory). The decision to approve tacrolimus for lung transplant based on RWE was an important step forward; however, this was limited as it was only for an expanded indication and not a new product. Given the cost of drug development, population size, and time for return on investment, immunosuppression research for Solid Organ Transplant has been limited. Therefore, novel approaches need to be adopted as discussed at a recent FDA consensus conference (https://www.fda.gov/media/126472/download), including adopting biomarkers and outcomes to assess efficacy.

Innovation has also been limited by the current structure of transplant regulation, management, and oversight. A single contractor has held the contract for the development and implementation of the Organ Procurement and Transplantation Network. In addition to direct policy development, organ placement, and center monitoring, the OPTN contractor has been the sole decision entity for technology

necessary to promote transplantation.[32] It has used its position as regulator, to promote products developed by a related corporate entity, to the detriment of other technology innovators. This has led to a slow development process and has stifled technological innovation.

Donor intervention trials have also proven to be difficult given the diversity of clinical environments and competing priorities. There is an immediate need to support donor intervention research, as recognized by the National Academy of Sciences, Engineering, and Medicine (https://www.ncbi.nlm.nih.gov/books/NBK458645/). Despite publication of this important work in 2017, no new interventional trials have been conducted on organ management.[33] Novel technologies which are successfully utilized outside of the U.S. (uncontrolled DCD, normothermic regional perfusion) have not been implemented within the U.S. transplant ecosystem.

Innovation in transplantation has resulted in lifesaving treatments for patients with advanced organ failure and no other options. These treatments extend life and often reduce long term costs. However, innovation in transplantation remains hampered by current regulatory policy:

- The transplant ecosystem is highly focused on early post-transplant outcomes, despite recent changes in the CMS CoP for transplant center recertification. Patients enrolled in clinical trials are included in a transplant program's outcomes assessment, which results in barriers to enrollment and innovation.

- Historically, FDA approval and CMS coverage decision policy contributed to a lack of innovation in the development of immunosuppression treatments. Given the cost of drug development, population size, and time for return on investment, immunosuppression research for Solid Organ Transplant has been limited.[34]

- A recent FDA consensus conference (https://www.fda.gov/media/126472/download), concluded that new pathways to drug approval need to be developed, including adopting of biomarkers and outcomes to assess efficacy. But the FDA recently declined an application to use an approved biomarker (iBox) to assess outcomes in clinical trials. Similarly, there has been a reluctance to consider Real World Evidence in drug approval, despite transplant registry data which meets all FDA requirements (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory).

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[32] Gentry SE, Segev DL. Restructuring the Organ Procurement and Transplantation Network contract to achieve policy coherence and infrastructure excellence. Am J Transplant. Jun 2019;19(6):1622-1627. doi:10.1111/ajt.15161.

[33] Freeman RB. Making a national donor research program a reality: Concepts for operationalizing a system. Am J Transplant. Oct 2019;19(10):2686-2691. doi:10.1111/ajt.15536.

Abt PL, Feng S. Organ Donor Research: It Is Time for Much Needed Clarity. Am J Transplant. Sep 2016;16(9):2508-9. doi:10.1111/ajt.13939.

[34] The decision to approve tacrolimus for lung transplant based on RWE was an important step forward, however, this was limited as it was only for an expanded indications and not a new product.

- Innovation has also been limited by the current structure of transplant regulation, management, and oversight.[35]

- The National Academy of Sciences, Engineering, and Medicine has recognized an immediate need to support donor intervention research (https://www.ncbi.nlm.nih.gov/books/NBK458645/); yet, due to the diversity of clinical environments and competing priorities, no new interventional trials have been conducted on organ management.[36]

As the result of these factors, novel technologies which are successfully utilized outside of the U.S. (uncontrolled DCD, normothermic regional perfusion) have not been implemented in the U.S.

RECOMMENDATIONS: To remove disincentives to innovation, ASTS supports:

- **Aligning current reporting across HHS (HRSA - UNOS/SRTR) to exclude outcomes for patients enrolled in IRB approved research protocols in transplant center quality metrics;**

- **Incorporating Real World Evidence in the CMS coverage determination and align with approval process with the FDA. Provide preliminary approval for novel strategies with appropriate Phase 4 monitoring.**

- **Including long-term cost savings in actuarial determination of cost in the budget assessment in applications for new services and payment reforms. For example, strategies to promote tolerance will have significant initial costs but promise clinical and economic benefit.**

- **Counting organs placed for research in the organ transplant rate. OPOs and surgeons need to be incentivized to obtain research authorization to promote innovation.**

- **Support Donor intervention research through CMS reimbursement and guidelines for OPO's, ORC, and transplant programs.**

The RFI, in raising the issue of outcomes requirements, questions why the elimination of CMS' outcomes requirements as a condition of Transplant Center (TC) recertification has not produced a dramatic increase in the number of transplants from organs at high risk of discard. We applaud CMS's decision to eliminate those action requirements, but we note that the reason this decision has not been more impactful is clear. Any impact of that laudable action by CMS has been attenuated or eliminated by the ongoing presence of Organ Procurement and Transplantation Network (OPTN) performance outcomes monitoring and the Scientific Registry of Transplant Recipients (SRTR) five-star rating system.

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[35] Gentry SE, Segev DL. Restructuring the Organ Procurement and Transplantation Network contract to achieve policy coherence and infrastructure excellence. Am J Transplant. Jun 2019;19(6):1622-1627. doi:10.1111/ajt.15161.

[36] Freeman RB. Making a national donor research program a reality: Concepts for operationalizing a system. Am J Transplant. Oct 2019;19(10):2686-2691. doi:10.1111/ajt.15536.

Abt PL, Feng S. Organ Donor Research: It Is Time for Much Needed Clarity. Am J Transplant. Sep 2016;16(9):2508-9. doi:10.1111/ajt.13939.

The elimination of CMS outcomes measures but continuation of OPTN outcomes measures means that, functionally, little has changed for transplant centers and their perception of the regulatory environment. The continuation of OPTN outcomes review continues to drive risk-averse Transplant Center organ and candidate decision-making.

The SRTR five-star rating system is potentially an even more important stimulus to risk aversion. The SRTR five-star system is different from the star ratings of the dialysis units which set predefined bars for performance in various clinical outcomes. The five-star rating system demands near perfect outcomes and can swing wildly based on tiny shifts in outcomes. Patients, referring physicians, and third-party payers rely heavily on star ratings and OPTN assessments, which change constantly and unpredictably. One adverse outcome can impact a Transplant Program's participation in a payer network for years to come. Continued risk aversion is the predictable and inevitable result.

Despite the presence of multiple drivers of risk-averse behavior and a complex regulatory regime, transplant centers and their organ procurement partners continue to drive the number of transplants performed to record numbers every year. Transplant programs have become more aggressive in their organ acceptance practices, and those aggressive practices are increasingly being adopted leading to the performance of the largest number of transplant ever in 2021. Decreasing the burden of regulation, better aligning stakeholders, making the allocation system more efficient at getting high-risk organs to the centers that have the requisite expertise to use them, and eliminating the five-star rating system could unleash even more increases in transplants by a system that desperately wants to serve more patients.

The need for action is particularly acute. The OPTN, under the auspices of HRSA, has recently adopted performance standards for Transplant Programs that, in our view, have the potential to increase disparities and organ wastage.[37] And while the RFI establishes as a goal the reduction in disparities, recent action by the SRTR in response to the COVID-19 epidemic demonstrates the lack of alignment. In attempting to give consideration to the impact of COVID-19 on transplant patient survival and the five-star ratings, the SRTR announced the exclusion from its transplant program ratings only those patient deaths that occurred during the first three months of the pandemic. By making this decision, the SRTR is threatening the public perception and private payer contracts of transplant programs located in geographic areas (including rural areas) where the pandemic hit later and transplant programs that serve a disproportionate share of minority recipients, since death rates from COVID-19 are between 1.9-2.2 times higher for Black, American Indian, or Hispanic compared to white or Asian persons. These transplant programs' COVID deaths are not appropriately excluded from outcomes analysis and the concomitant changes in these centers' star ratings may threaten patient access to them.

[37] See Attachment G: ASTS comments on the OPTN Proposal "Enhance Transplant Program Performance Monitoring System," September 30, 2021.

Attachment A

ASTS Letter to HHS Secretary Tom Price, Sept. 11, 2017

Via e-mail

September 11, 2017

Thomas E. Price, MD
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Re: American Society of Transplant Surgeons Request for Regulatory Relief

Dear Secretary Price:

On behalf of the American Society of Transplant Surgeons, we applaud your initiative to minimize regulatory burdens on physicians that interfere with the efficient and effective delivery of high quality care. Along these lines, we strongly believe that this initiative should address the current duplicative regulation of transplant centers (TCs) by both the Centers for Medicare and Medicaid Services (CMS) and the Organ Procurement and Transplantation Network (OPTN) under the auspices of the Health Resources and Services Administration (HRSA). This letter sets forth an overview of the problem, a proposed framework for addressing it, and proposed next steps.

I. Overview

A. In General

For the past several years, the transplant community has been facing a steadily mounting burden of oversight that is now threatening the creative and vibrant spirit that has marked the field since its inception, like the frog in the old adage sitting in slowly heating water until it finds itself boiling. We recognize the complexity of our enterprise and embrace the challenge of caring for our patients with compassion and expertise. We also welcome the opportunity to seek ever-improving results in a safe and reliable patient care system. We are proud to publicly demonstrate our outcomes and our ever-improving processes to ensure patient safety and fairness to all who need a transplant. However, despite the culture of pride and innovation that permeates our community, individual infractions by a small number of transplant programs have led to an overwhelming burden of oversight on transplantation and transplantation-related care.

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Under current law, both the OPTN and CMS impose both process and outcomes requirements on TCs. The CMS and OPTN outcomes requirements differ, and for that reason the TCs identified for review by the OPTN and those identified as out of compliance with Medicare approval requirements differ. In addition, the OPTN and CMS impose different process requirements on transplant centers, and their methods of ensuring compliance with several of the common requirements differ. A crosswalk of CMS and OPTN requirements available on the OPTN website suggests that, together, there are approximately 123 requirements (a number that we believe to be underestimated), approximately 30% of which are reviewed by both CMS and the OPTN. The remaining requirements relate principally to Quality Assurance & Performance Improvement (QAPI) and multi-disciplinary team requirements imposed by CMS but not the OPTN, differing review processes for pediatric and adult programs, differing volume (clinical experience) requirements, and differing waitlist management and notification requirements. Both the CMS and the OPTN regulatory processes require extensive review of medical records. This duplication of regulatory requirements is costly both for TCs and for the federal government (and its paid private contractors), and unnecessarily distracts time and attention from patient care. Preparation for a CMS or OPTN survey is a months-long process requiring hundreds of FTE hours as well as considerable physical resources. Both surveys require an egregious waste of paper, when it could all likely be done electronically. Moreover, both sets of requirements are overly prescriptive and interfere with the patient-physician relationship and with physician judgment in the context of complex clinical decision-making.

The imposition of these extraordinarily burdensome regulatory requirements is particularly inappropriate in light of the extremely demanding outcomes requirements imposed by both the OPTN and CMS. Both CMS and the OPTN impose strict patient and graft one-year survival requirements that dissuade TCs from accepting "suboptimal" organs. Post-transplant organ graft and patient survival expectations are set significantly higher for transplantation than other diseases like cancer, which has a 66.9% five-year survival rate. As the chart below illustrates, transplantation truly has excellent outcomes and ideally should be made available to a greater number of recipients.[1]

	One-Year		Three-Year		Five-Year	
Organ	2017 Report	2014 Report*	2017 Report	2014 Report*	2017 Report	2014 Report*
Heart	91%	89%	85%	82%	78%	75%
Intestine	81	80	67	63	58	53
Kidney	97	96	93	92	86	86
Liver	91	89	83	81	75	74
Lung (Single and Double)	87	85	69	66	55	51
Pancreas	92	93	88	89	80	81
Heart-Lung	80	73	59	54	51	45
Kidney-Pancreas	98	96	95	92	88	87

[1] Bently, "2017 US Organ and Tissue Transplant Cost Estimates and Discussion," Milliman Research Report, 2017. http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf. By comparison the US 5-Year Relative Survival for all cancers is 66.9% according to the National Cancer Institute SEER Cancer Statistics Review. (https://seer.cancer.gov/archive/csr/1975_2013/results_single/sect_01_table.05_2pgs.pdf

In light of the excellent outcomes achieved by TCs, it is unclear to us why such extraordinarily onerous "process" requirements are considered necessary by not only one government agency, but two.

B. Some Examples

The overlapping (and sometimes conflicting) morass of TC regulatory requirements imposed by both CMS and the OPTN are ripe for simplification and streamlining. Not only are these requirements duplicative, they are also extraordinarily detailed. For example:

- The OPTN regulatory requirements include 230 pages of policy, 180 pages of Bylaws, and 65 pages of Evaluation Plan. [2]
- CMS regulatory requirements includes 85 pages of the Federal Register, 107 pages of the Survey and Certification Interpretive Guidelines, 50 pages of Survey and Certification Interpretive Guideline Changes, 49 pages of Quality Assessment and Performance Improvement (QAPI) Program requirements, 103 pages of updated Interpretive Guidelines (pending revisions May 2016), and numerous additional updates and clarifications. [3]

- **Organ and Vessel Tracking**
    - The time out and verification process has been cumbersome. Requirements in this area have been characterized by variation in surveyor preference between the OPTN and CMS and by each agency's practice of changing its own regulatory requirements, in an asynchronous manner over time. Forms developed by the OPTN do not meet the

[2] https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf

https://optn.transplant.hrsa.gov/media/1202/evaluation_plan.pdf.

[3] See, e.g.
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/Transplantfinal.pdf;

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-25.pdf;

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-09.pdf;

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

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-10.pdf

requirements of CMS surveyors, and CMS and OPTN surveyors have imposed different requirements regarding electronic documentation in the Electronic Medical Record (EMR) versus paper copy and signatures.

- **Patient Education and Consent to Proceed**
    - It is critical that patients and living donors are well informed of the risks, benefits, and alternatives to participation in the various phases of transplant and donation. However, regulations call these encounters "Informed Consent" which create unnecessary concern from the patient and confusion with legal and risk departments within a hospital. The OPTN consent requirements are incredibly prescriptive yet they do not provide a templated form for use. TCs find themselves constantly updating the forms to include small language changes, only to then be cited for missing something miniscule. Meeting these informed consent requirements has resulted in extremely lengthy documents and encounters to "cover all bases," which are overwhelming to both recipients and potential donors, and which add significant physician time.

- **Time Requirements and Disparate Timeframes**
    - The OPTN and CMS are on separate timelines for completing onsite and offsite surveys. Often TCs encounter both teams within a given year, resulting in 3-5 days of interruption for each visit. OPTN surveys are scheduled and CMS surveys are unscheduled. These agencies do not coordinate TC survey schedules, which has resulted in disruption of TC hospital and clinical operations. Survey readiness, even when scheduled, also necessitates significant TC financial and resource commitment. In addition, significant team time is required to implement plans of correction, education, and auditing after the visit. Surveys are useful tools when they result in process improvements; however, typically these surveys result in more administrative work, redundant documentation, and team time away from clinical care. In one large center, over 60 staff are occupied full time at the expense of patient care and other duties the week of the CMS survey.

- **Clinical Micromanagement**
    - Process oversight extends to the micromanagement of educational materials provided to patients and specific documentation requirements of the role of social workers and others in the overall care of patients in multiple locations. For example, the transplant nephrologist must document the results of the psychiatric assessment *even when* the consultation report of the psychiatrist is part of the patient's chart.

- **ABO Verification**
    - A single highly publicized misallocation of a heart by blood type led to a process of verification of blood types prior to transplantation that has grown into a morass of checklists and forms, which are dated and timed and avidly reviewed by surveyors for spelling errors and marks in the wrong box. Up to 63 points of failure have been identified in form completions and design. Compliance with this regulation has led to a substantial number of new administrative positions to oversee the work of the clinicians and evaluate form completion and requirements. While well intentioned, these processes do not contribute to patient safety, only paperwork and administrative burden.

C. Statutory Authority

Despite the extraordinary level of detailed oversight imposed by both CMS and the OPTN, neither Medicare certification nor OPTN TC review processes are clearly or unequivocally required by statute. Section 1881(b)(1) of the Social Security Act (the "Act") gives the Secretary authority to prescribe regulations for payment for renal transplantation services; however, there does not appear to be any specific statutory authority mandating certification of renal transplant programs, and no provision of the Act of which we are aware mandates the establishment of any type of specialized certification requirements for other forms of transplantation. In fact, CMS only adopted specific certification regulations for TCs in March of 2007, as the result of earlier public and Congressional concerns raised in response to certain highly publicized lapses by a handful of TCs. Before that time, CMS relied entirely on the OPTN to oversee TCs, since Section 1138 (a)(1)(B) of the Social Security Act, enacted in 1986, requires Medicare and Medicaid participating hospitals that perform organ transplants to be members of and abide by the rules and requirements of the OPTN. CMS relied on its general rulemaking authority to publish rules and regulations ''necessary for the efficient administration of the functions" of the Medicare Program to adopt the final TC certification regulations, which reflects the lack of specific statutory authority to establish TC certification requirements independent of OPTN membership criteria.

The OPTN was established by the National Organ Transplant Act (NOTA) (PUBLIC LAW 98-507-OCT. 19, 1984), and Section 372(b)(2) of NOTA sets forth with specificity the responsibilities of the OPTN. None of these explicitly requires the OPTN to establish quality requirements for TCs; however, NOTA does indicate that the OPTN has the responsibility to establish its own membership standards,[4] and it appears that this is the sole statutory basis for the OPTN's extensive oversight of TCs. While it may be argued that comprehensive oversight of TCs by the OPTN was necessary when the OPTN was the only body charged with ensuring that TCs maintained quality standards, since the adoption of Medicare certification standards, that is no longer the case.

II. A Proposed Framework to Reduce TC Regulatory Burden

A. Principles to Guide TC Regulatory Reform

Because TC regulatory requirements are imposed by two separate and independent agencies within HHS and because the requirements imposed by both agencies are detailed and complex, administrative simplification in this arena may prove challenging. For this reason, the administrative simplification process should be guided by clear and easily understood basic principles, the objective of which is to preserve transplant quality and patient protections, while simplifying and streamlining oversight. Specifically, we strongly believe that the regulatory review process should result in:

- One set of TC oversight regulations and regulatory interpretation;
- One set of TC outcomes measures intended to maximize transplantation rates;
- One combined survey conducted as necessary based on a single set of survey triggers; and
- One set of consequences for noncompliance.

We refer to these objectives as the "Reform Principles."

[4] 42 USC §274(b)(2)(B)

B. Operationalizing the Reform Principles

The Reform Principles could be operationalized in any number of ways. As discussed above, currently the OPTN and CMS oversee and monitor both outcomes and process. However, it may be possible to apply the Reform Principles by providing one of the two agencies with the authority to establish outcomes requirements while the other establishes process requirements, or, following historical areas of special competence, the OPTN might be given primary responsibility for establishing the requirements for activities and processes that occur outside the four walls of the TC (e.g., organ retrieval, allocation and distribution, patient ranking on the waitlist, and ensuring the fairness of waitlist processes), while CMS retains primary authority to establish rules related to TC activities, including QAPI (an area in which CMS and its contractor have established special experience and expertise).

However, in our experience, each of the two agencies has considerable expertise that the other does not, and the ideal regulatory framework would involve close collaboration of CMS and the OPTN/HRSA to establish a single integrated regulatory framework and oversight process. For this reason, we urge the Secretary to consider a TC regulatory framework with the following characteristics:

- Approval of New TCs: Currently, CMS does not regulate TCs until they become operational, and the job of approving new centers falls to the OPTN. We believe that this allocation of responsibility is appropriate and that, while the OPTN requirements for new centers should be reviewed and streamlined to the extent practicable, the OPTN should retain the responsibility for initial TC approval.

- Organ Retrieval and Allocation, Waitlist Management, and Related Data Management: Likewise, the OPTN has considerable expertise in the area of waitlist management and oversight, and has comprehensive processes in place to ensure that waitlist rules are not subject to "gaming." In addition, the OPTN routinely engages in considerable data collection to ensure compliance with organ allocation and distribution policies. In operationalizing the Reform Principles, we urge the Secretary to direct the OPTN/HRSA to review its current standards related to these and other areas that take place outside the "four walls" of the TC, but to retain OPTN/HRSA sole oversight authority in these areas. To the extent that on-site surveys must be conducted to ensure compliance with such waitlist, allocation or other rules, the survey should be conducted as part of a unified OPTN/HRSA/CMS survey (discussed below).

- Establishment of Interagency Committee: We urge the Secretary to appoint an interagency committee ("Interagency Committee") composed of representatives appointed by CMS, HRSA, and the OPTN, to operationalize the Reform Principles and to enforce compliance. The tasks of the Interagency Committee should include at least the following:

    - Unified Outcomes Requirements: Under current rules, TCs' one-year outcomes, as reported and risk adjusted by the Scientific Registry of Transplant Recipients (a HRSA contractor), are assessed by CMS and by the OPTN using different statistical standards, resulting in the "flagging" of different centers and different times by the two agencies. We urge the Secretary to direct CMS and the OPTN/HRSA to establish a single set of TC outcomes standards and to modify Medicare certification regulations and/or OPTN Bylaws and policies as necessary to adopt the agreed outcomes standards.

- Streamlined Process Requirements Focused on Transparency and Due Process: TCs are among the only, if not the only, type of provider, other than Organ Procurement Organizations (OPOs) that are required to comply with both outcomes requirements and comprehensive process requirements as a condition of participation in the Medicare Program. Each TC publicly reports its individual patient and organ survival statistics, and, under current Medicare certification standards, a TC that reports lower than expected patient and graft survival for two years fails to meet Medicare certification standards. We do not believe that TCs that maintain high outcomes standards also should be subject to comprehensive process requirements related to various aspects of clinical care. Since outcomes standards are generally viewed as out-of-reach for many types of providers, Medicare certification requirements generally focus on compliance with processes thought to contribute to positive outcomes. In the absence of outcomes standards that are definable and enforceable, the imposition of process requirements is viewed as the "best that can be done." Where, as in the case of TCs, outcomes standards are available and applied on a continual basis, why should CMS or OPTN also impose comprehensive and detailed process requirements related to various aspects of clinical care? On the other hand, there are certain transparency and due process standards that all TCs should maintain regardless of the outcomes they achieve. We believe that it is in these areas that process requirements and oversight surveys should focus:

  - ✓ Patient rights
  - ✓ Core safety measures
  - ✓ QAPI programs
  - ✓ Care of living donors

- Non-Prescriptive Interpretive Guidelines: Currently, much of the burden of compliance with both CMS and OPTN regulatory requirements arises not because of the basic CMS regulations and OPTN Bylaws or policies, but because of the overly prescriptive manner in which these requirements are applied by surveyors from the two agencies. The Interpretive Guidelines used by surveyors under contract with CMS are currently over 100 pages in length, and an equally long revision is currently on hold as the result of substantial objections from the TC community.[5] Likewise OPTN surveyors utilize a comparable 65 page document, the OPTN Evaluation Plan, in conducting OPTN surveys, of approximately equal length. We urge the Secretary to direct the Interagency Committee to develop a single interpretive document to be used by those conducting surveys of compliance with those relatively limited process requirements that are retained, and that, in developing this document, the Interagency Committee should be requested to use the following guidelines:

  - ✓ The Interagency Committee should develop Interpretive Guidelines with the clear objective of minimizing administrative burden. Care should be taken to ensure that the Interpretive Guidelines stay within the scope of limited process requirements.

[5] See current Interpretive Guidelines at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-25.pdf and proposed revision at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-10.pdf.

- ✓ The Interpretive Guidelines should be developed with input from the transplant community.
- ✓ When CMS and the OPTN both have current interpretive documents relating to the same basic requirement, the least prescriptive guideline should be adopted as the model.
- ✓ To the extent that TCs are expected to utilize a particular form or process, a model document should be provided to the transplant community.

- Triggers for Oversight Survey: Oversight surveys should be performed in a coordinated fashion and should involve surveyors from both CMS and the OPTN, working together. Surveys should be performed under well-defined circumstances, such as:

  - ✓ Failure to meet outcomes thresholds
  - ✓ Major sentinel events
  - ✓ Failure to comply with OPTN rules regarding listing and allocation practices

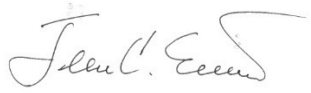
- Consequences of Failure to Comply with Process/Meet Outcomes Standards: The Interagency Committee should merge the OPTN and CMS plan of correction/mitigating circumstances processes; review of TC performance should be conducted jointly by the OPTN/SRTR and CMS; and the process should draw upon the expertise of the OPTN Membership and Professional Standards Committee (MPSC).

III. Next Steps

The reforms outlined above likely would require modification of the CMS Conditions of Participation for TC and OPTN Policies (and possibly Bylaws). It is also possible that the task of streamlining the TC review process should be included in the scope of services set forth in the Request for Proposals to be issued by HRSA for the OPTN contract, which we understand will be released this Fall.

We would be delighted to meet with CMS, OPTN, and HRSA representatives to discuss the next steps in developing a unified, streamlined, and effective TC oversight process. If we can provide any further information regarding our concerns or proposed framework for addressing the overregulation of TCs, please do not hesitate to contact Kim Gifford, ASTS Executive Director, at kim.gifford@asts.org or 703-414-7870.

Sincerely yours,



Jean C. Emond, MD
President
American Society of Transplant Surgeons

Attachment B

ASTS Presentation for HRSA/CMS Joint Meeting, March 17, 2021

The Need for A New Perspective on Transplant Regulation

American Society of Transplant Surgeons
Centers for Medicare and Medicaid Services
Health Resources and Services Administration

MARCH 17, 2021 4:00-5:00 P.M. (ET)

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Meeting Agenda

I. Introductions and Goals

II. Transplantation and Transplant Center Regulation: Background

III. The Immediate Need: Elimination of Disincentives to Transplant Organs at Risk of Discard

IV. The Longer-Term Challenge: The Need for Close Coordination to Increase Access

V. Discussion

Our Goals

To increase access to transplantation as a treatment option

1. **Eliminating disincentives to transplantation**
   - Current metrics used in Organ Procurement and Transplantation Network (OPTN) Transplant Center performance evaluation
   - Public "star ratings" calculated by the Scientific Registry of Transplant Recipients (SRTR)
2. **Coordination and cooperation** among various agencies that regulate transplantation and the transplant community
3. **Align provider incentives** within the transplant ecosystem

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Transplantation and Transplant Center Regulation: Background

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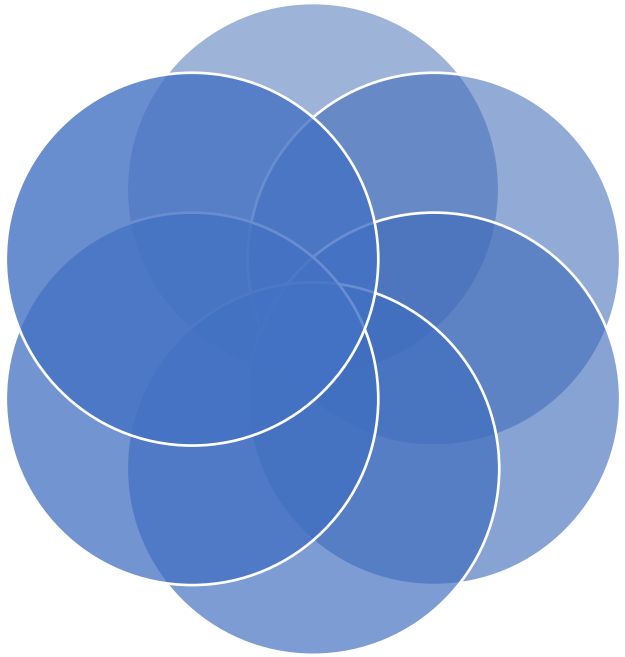
Transplant Ecosystem

Donor Hospitals

Regulatory Agencies



OPOs

OPTN/ Allocation

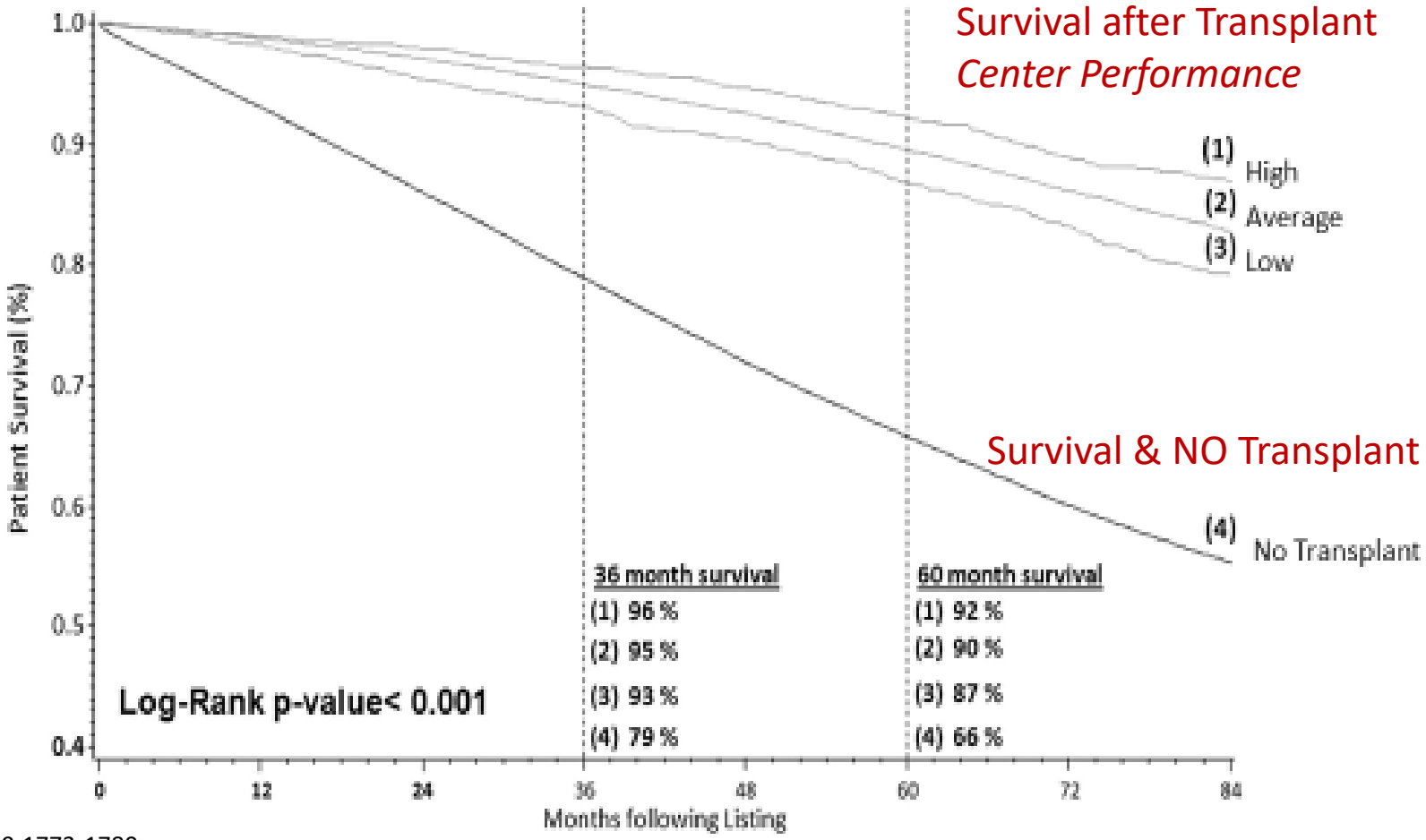
Transplant Centers

Payers

Putting Transplant Outcomes in Perspective

Need to Eliminate Disincentives to Using Organs at Risk of Discard

Kidney Transplant Always Yields Better Survival than No Transplant



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

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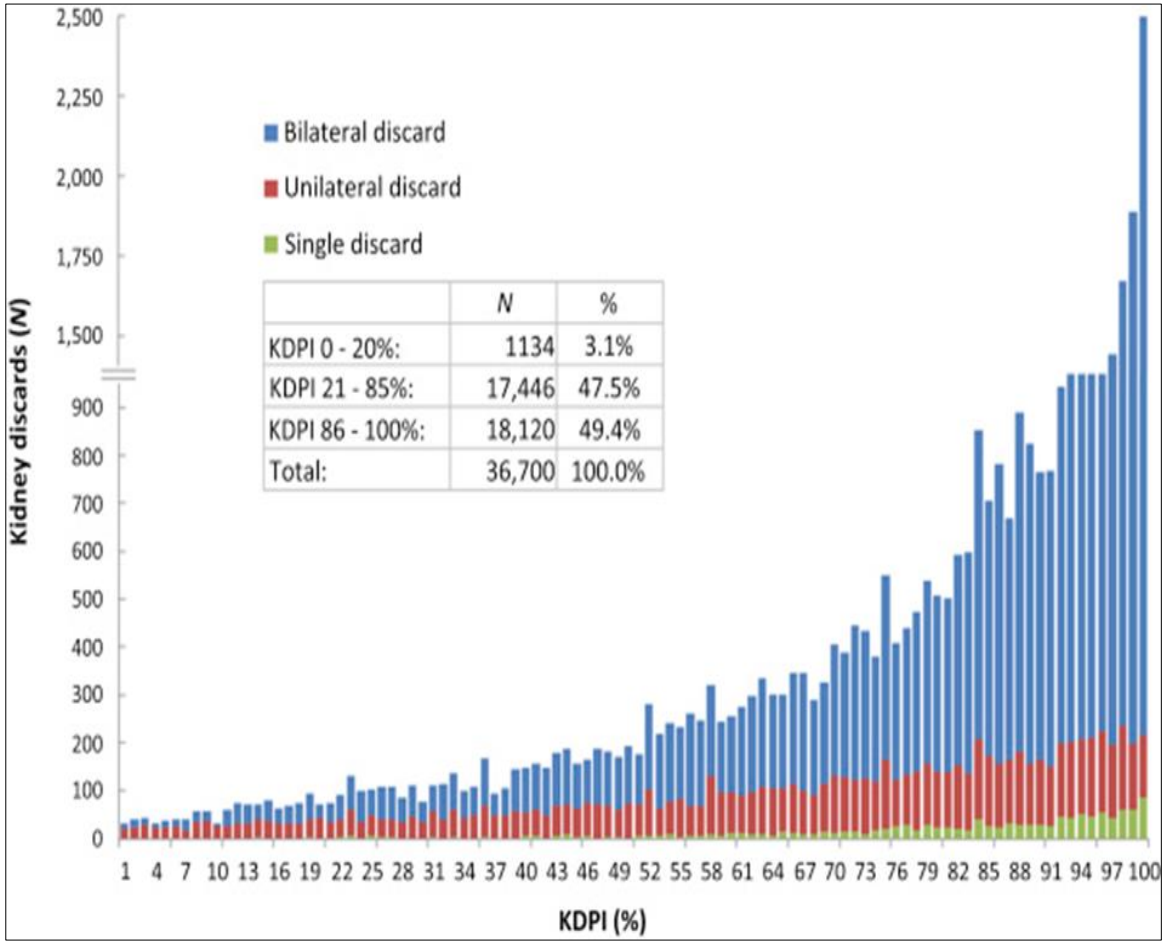
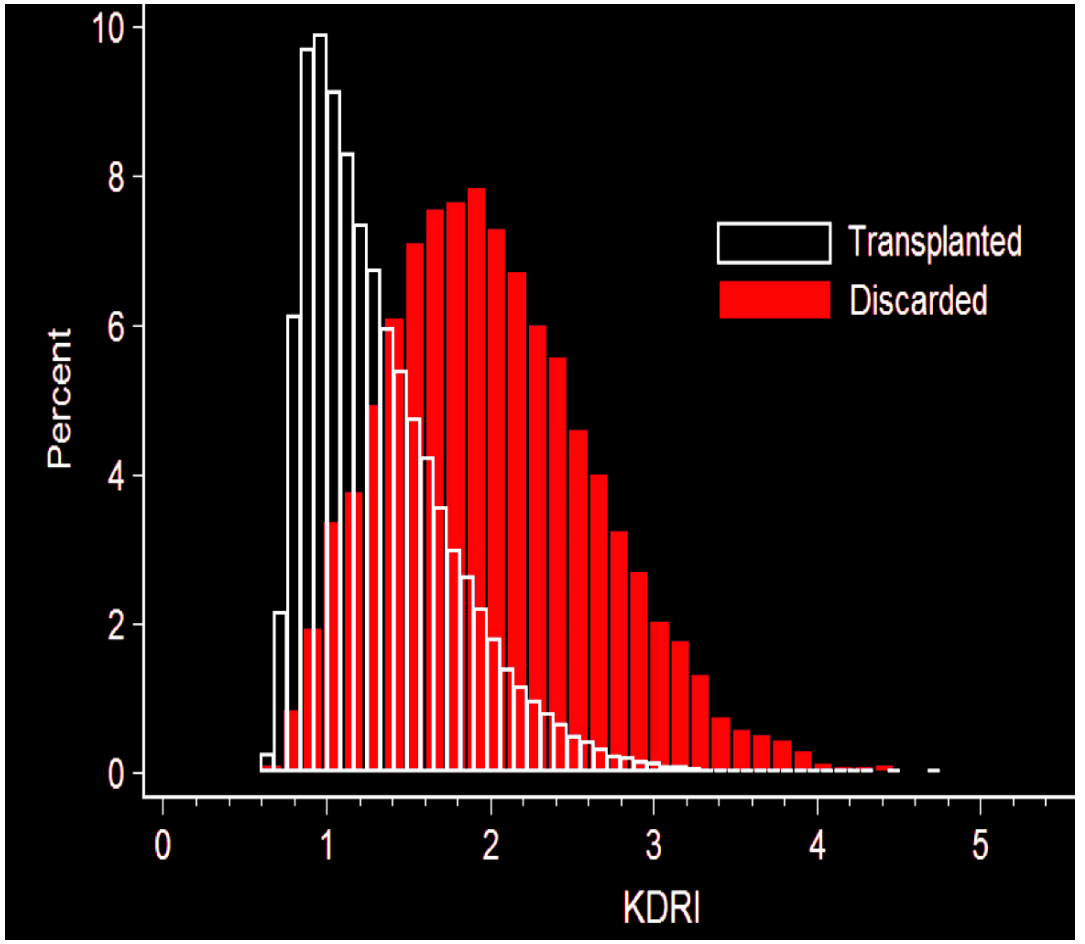
Risk Adjustment Contributes to Kidney Discard





Duplicative Regulation of Transplant Center Quality through HRSA and CMS

- NOTA does not include regulation of TCs as an OPTN function:
  - But does give the OPTN authority to establish its own membership criteria, so long as all Medicare-certified TCs qualify as OPTN members.
- OPTN involvement in overseeing Transplant Centers pre-dates Medicare Conditions of Participation (CoPs) for TCs.
- As a result, Transplant Centers are required to comply with overlapping, duplicative and sometimes conflicting regulation by CMS and by the OPTN.

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Timeline of Transplant Program Quality Oversight

- 1984: NOTA - establishes OPTN contract
- 1987: SRTR contract issued by HRSA

- 1992: First transplant center specific reports issued
- 1999: Center specific reports first reported on internet

- 2007: CMS issues CoPs

- 2012: HRSA sponsors Consensus conference
- 2014: SRTR revises statistical models adopted by MPSC

- 2017: CMS revises COP including increased SMR for flagging threshold
- 2017: SRTR issues 5-Tier Ratings

- 2018: Revised 5-Tier Ratings on Beta SRTR site
- 2019: CMS eliminated 1-year outcomes requirements as a condition of TC recertification

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Current Oversight of Transplant Quality (CMS)

- **Medicare CoPs include:** patient and living donor selection requirements, organ recovery and receipt, patient and living donor management, waitlist management, patient records, QAPI, staffing Adverse Events reporting and other requirements.

- **CMS QAPI CoP provides:** the transplant center's QAPI program must use objective measures to evaluate the center's performance regarding transplantation activities and outcomes. **Outcome measures** may include: (but are not limited to) patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, patient education, patient satisfaction, and patient rights.

Current Oversight of Transplant Quality (CMS)

- **F-QAPI surveys** conducted, beginning in 2014, for any transplant center that applies for approval or reapproval of certification.

- Medicare outcomes requirements eliminated as a condition of recertification at the end of 2019 due to impact on Transplant Centers' risk aversion.

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Current Oversight of Transplant Quality HRSA (OPTN and SRTR)

- OPTN Review of Transplant Centers includes:
  - Membership Criteria Reviews
  - Transplant Hospital On-Site Reviews (every 3 years) (includes data validation, medical record reviews, transplant hospital policy and protocol reviews, hospital staff interviews, and educational demonstrations)
  - Transplant Hospital Desk Reviews
  - Patient Safety and Non-Routine Compliance Reviews
  - MPSC Compliance Review (blinded case review)
  - Transplant Program Outcomes Review
  - Transplant Program Activity Review (3x/year)
  - MPSC Performance Review
  - Peer Visits
- Program Specific Reports (public), including Transplant Center star ratings

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The Need To Eliminate Current Disincentives to Transplantation of Organs at Risk of Discard

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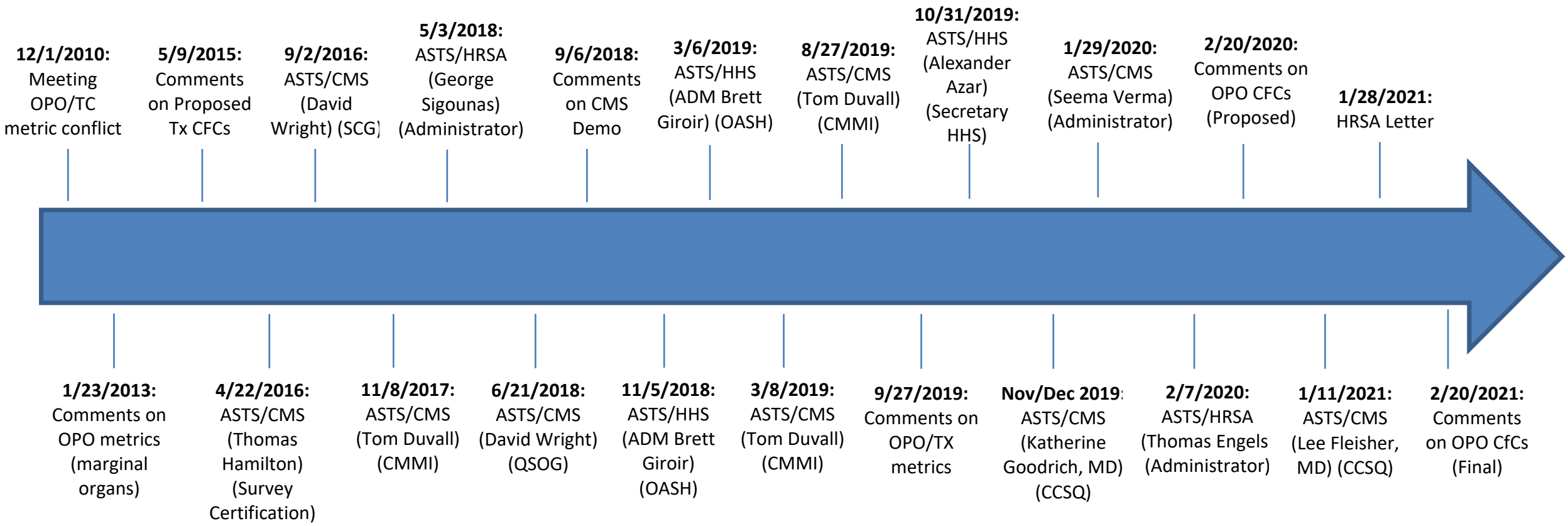
The ASTS Efforts to Remove Disincentives



New OPO CoPs will place extraordinary pressure on OPOs and TCs to use organs at risk of discard - OPO performance 2024

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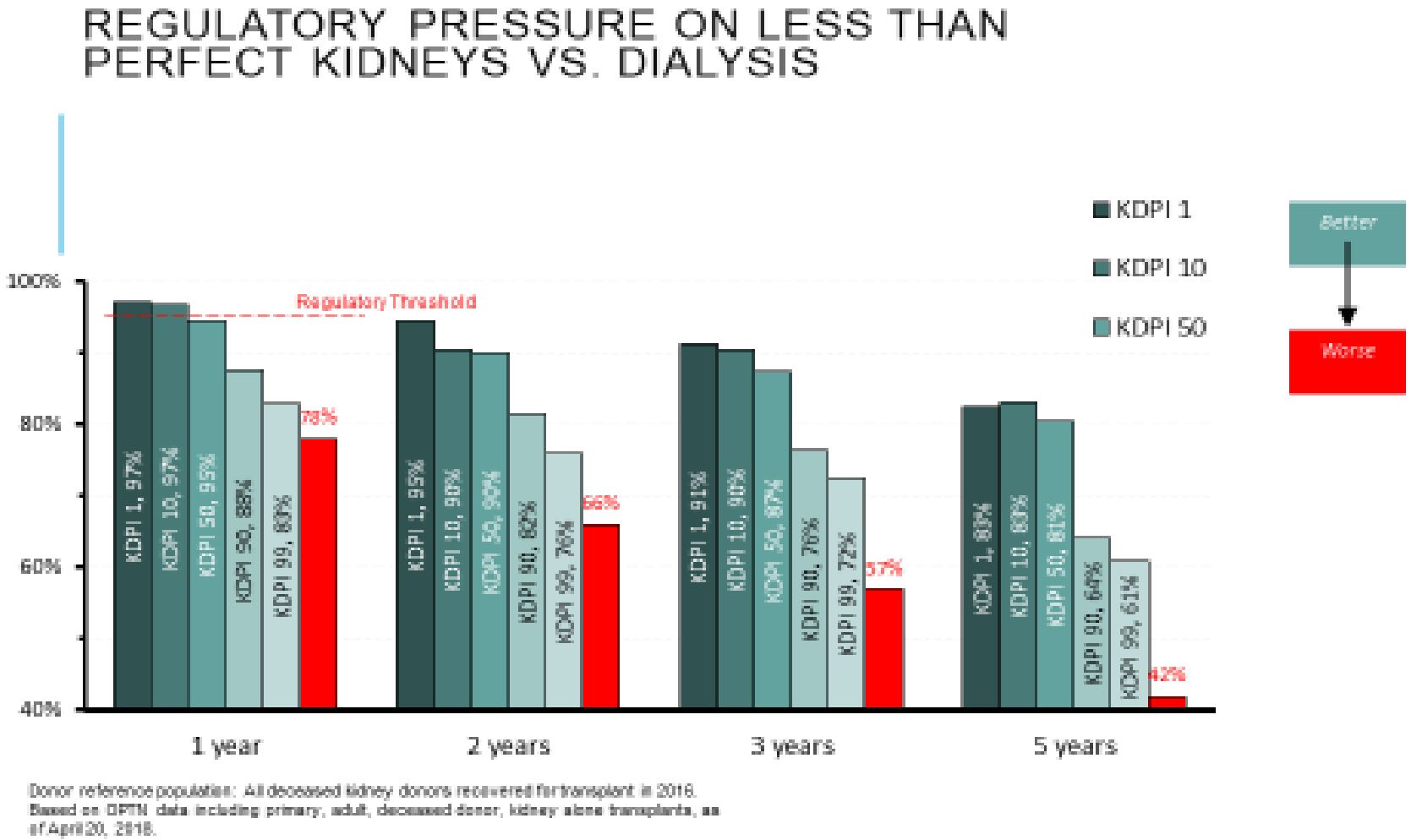
Why Transplant Centers Hesitate to Use Lower KDPI Organs in the Face of Regulatory Scrutiny of Outcomes



"Marginal" (higher KDPI) kidneys are associated with lower transplant success rates, but data demonstrates that even the most marginal kidney transplants have better outcomes than remaining on dialysis.

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Disincentives to Use "Marginal" Organs: **Star Ratings**

- In 2018, the SRTR (with the approval of HRSA) implemented a five-star rating system for TCs.
- A TC's stars for one-year outcomes are displayed prominently on the web.
- Stars compare a Transplant Center's performance with "expected" performance based on SRTR risk adjustment and other modeling.
  - For example, a Transplant Program with three (3) stars is performing "as expected."
  - Star rating is not consistent with general use of ratings most familiar to patients (e.g. restaurants, lodging ratings).
- Star ratings are used by:
  - Patients to determine where to get waitlisted; and
  - Payers to determine assess determine whether to include (or continue to include) a TC in its network.

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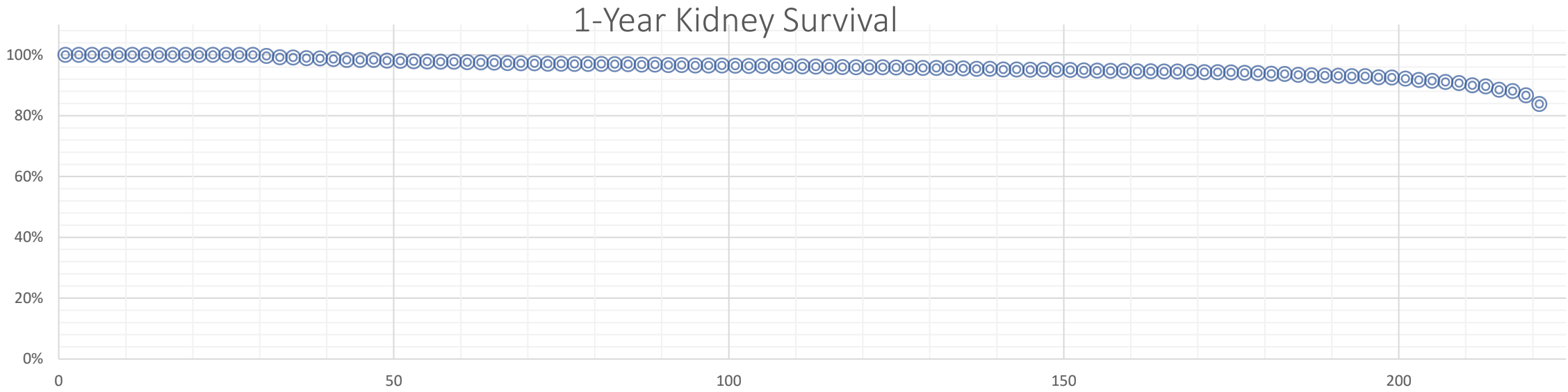
Distinction with (Little) Difference: One Year Outcomes and Star Ratings



1-Year kidney Survival (% with functioning transplant at 1 year)	93	94	96	97	98

The most recent SRTR data indicates that the one-year outcomes for even “one star” TCs is 93% patient/graft survival!

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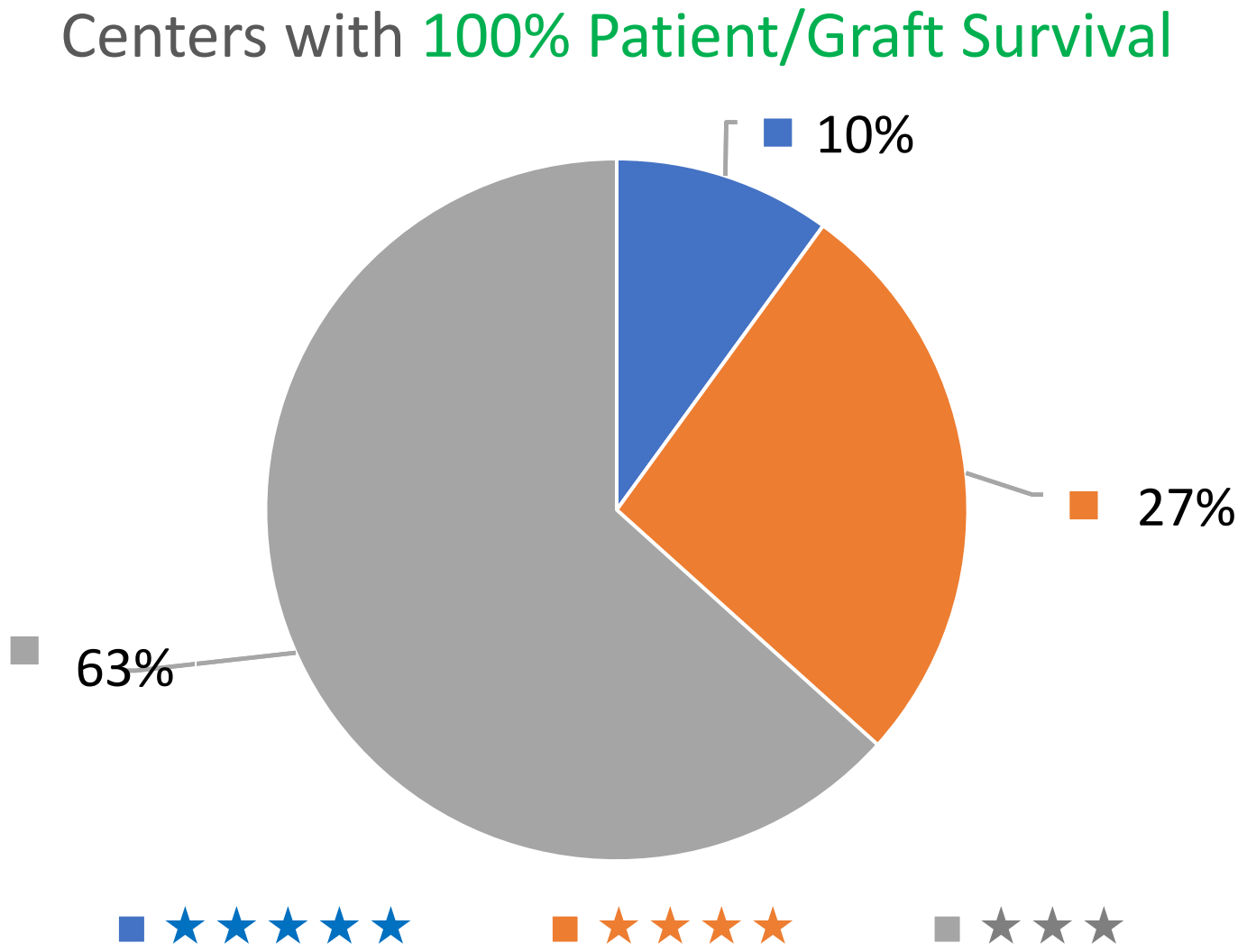
Digging into the Star Ratings: What does the Most Recent Data Show?



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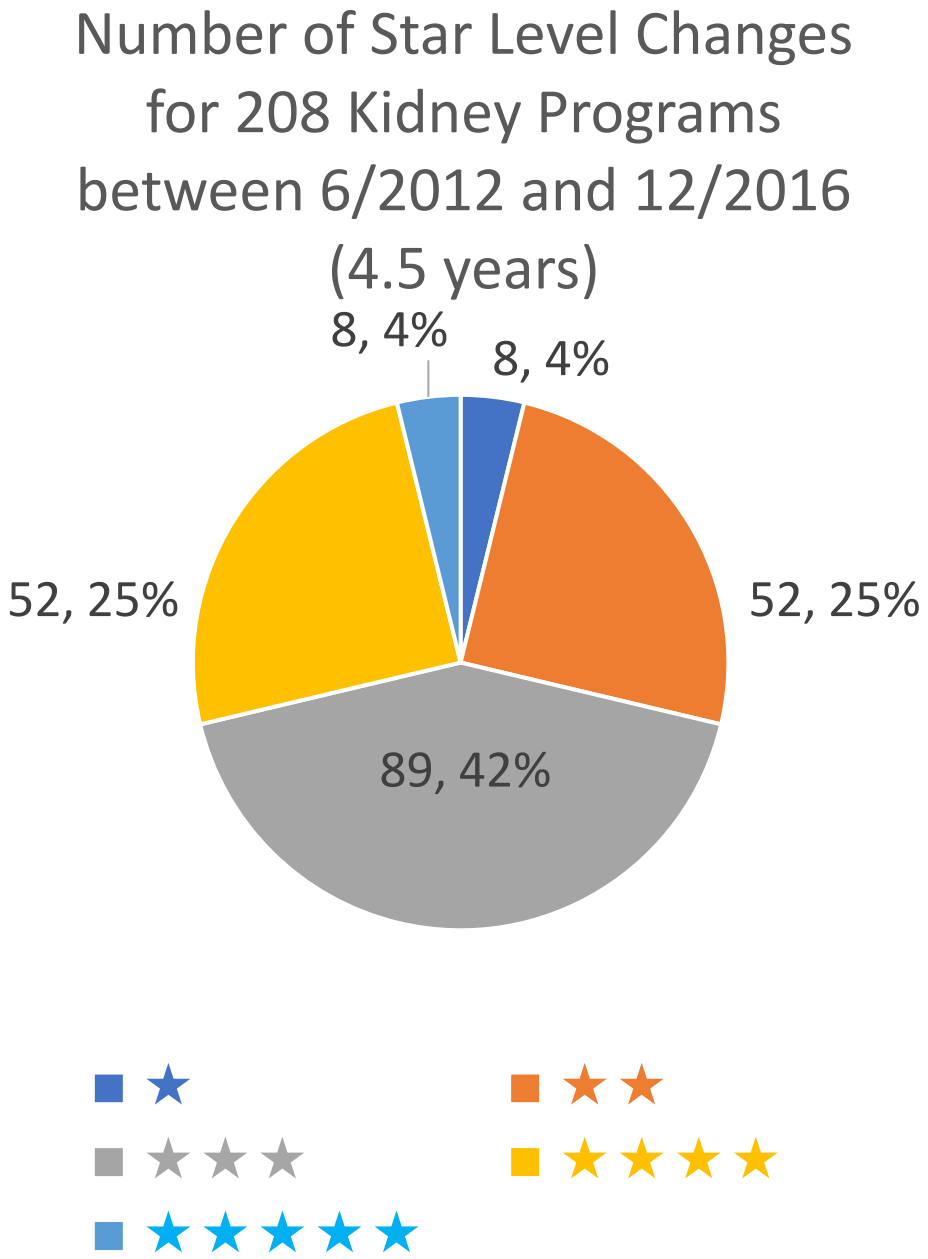
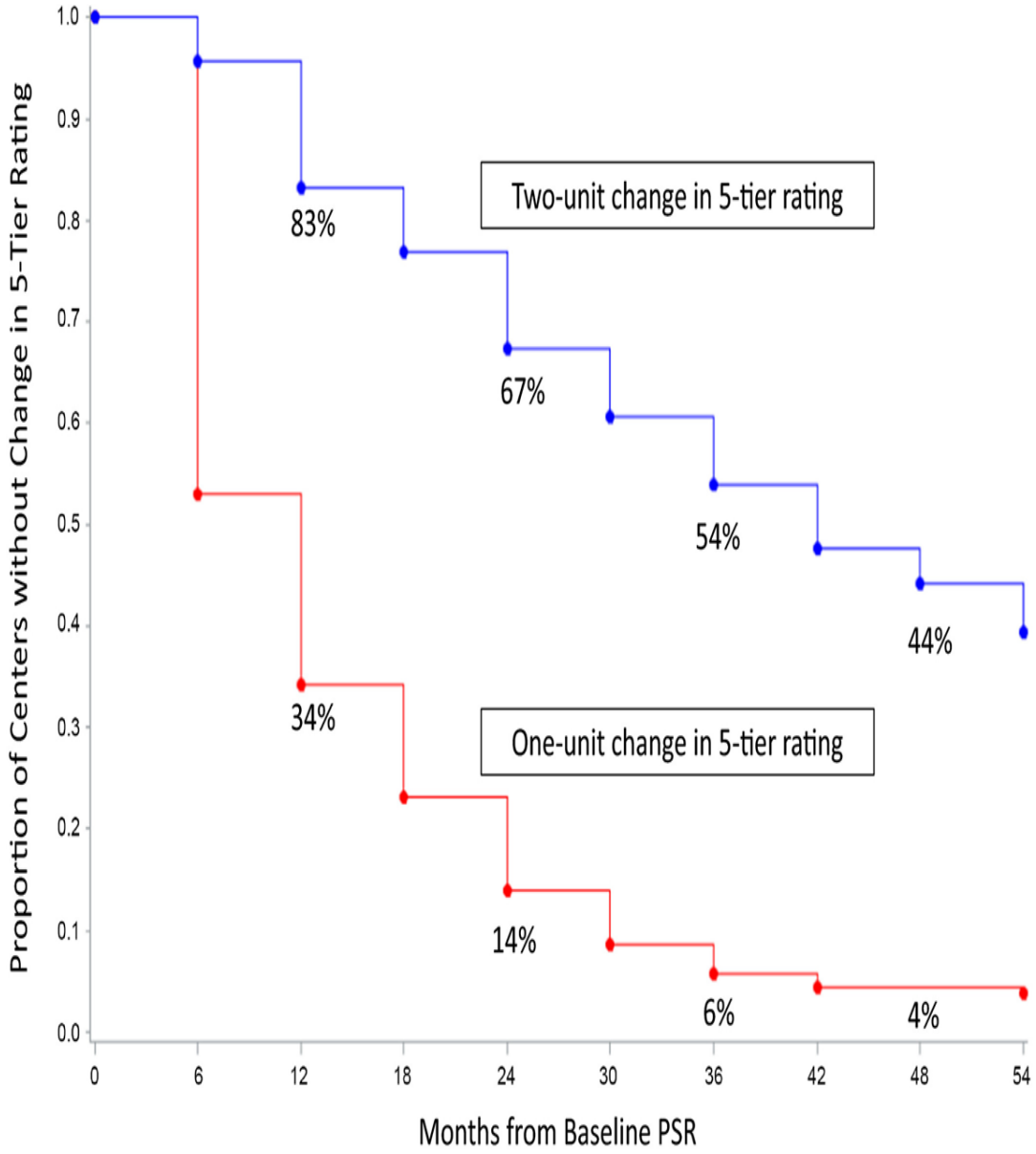
Volatility of Star Ratings





Negative Impact of Changes in Star Ratings

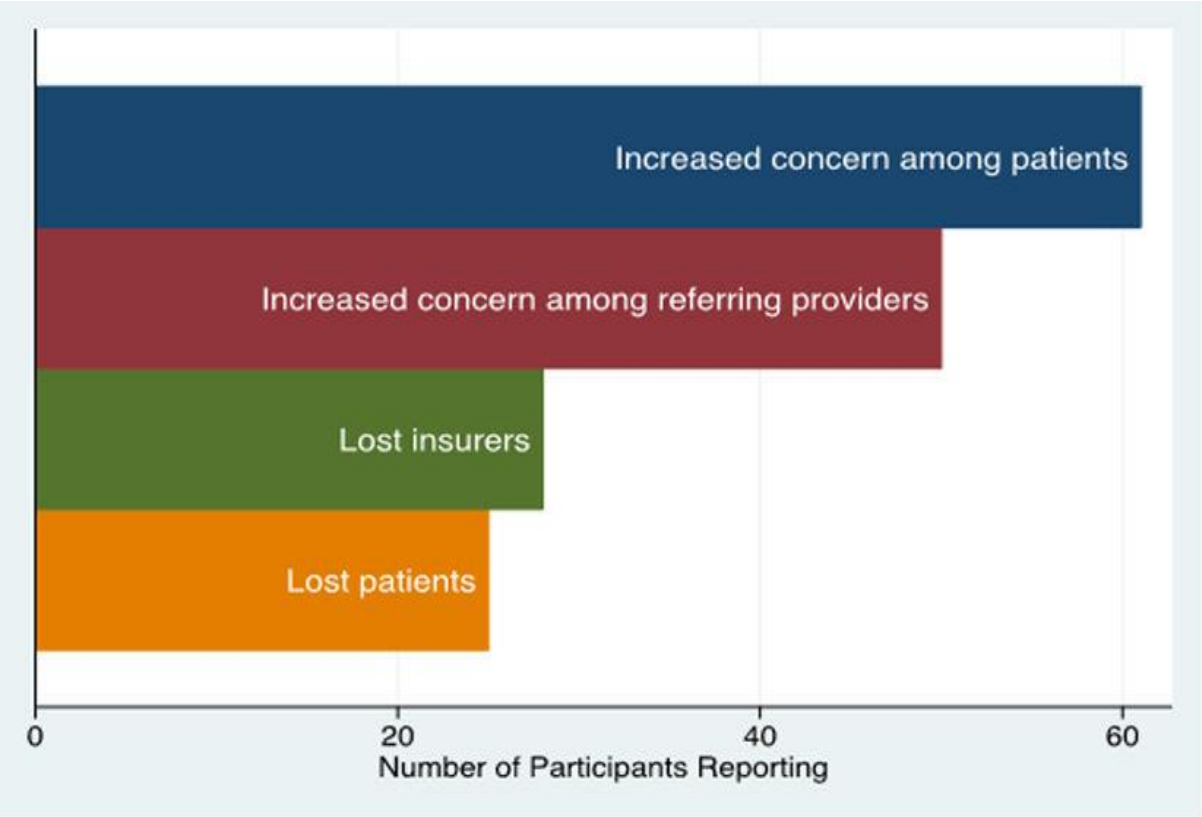


Figure 3: Reports of negative effects of the SRTR 5-tier rating system. Survey respondents were given a list of four positive and four negative potential effects of the SRTR 5-tier system and were asked if their transplant hospital experienced any of these effects. Shown are the number of respondents who reported each of the negative potential effects: increased concern among patients, increased concern among referring providers, lost insurers, and lost patients.

Van Pilsum Rasmussen et al. Page 13

N=240

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OPTN/MPSC
TC Outcomes Performance Reviews

- A significant number of kidney transplant programs are identified as Low Performers (LPs) according to OPTN flagging criteria despite relatively small survival differences compared with expected.

- Problem: The risk adjustment models need further refinement (models have an approximate concordance index of 0.65, coin toss concordance index = .5)

OPTN/MPSC
TC Outcomes Performance Reviews

Consequences of OPTN/MPSC and other “flagging”

- Mean decline of 22.4 transplants annually in centers with a LP Program Specific Report compared with an average 7.8 transplant increase annually for other centers during the same time period
  - Almost a quarter of kidney transplant centers had an LP report during this period.
- Studies have demonstrated a significant decline in the proportion of patients who had private primary insurance in centers with a LP evaluation.

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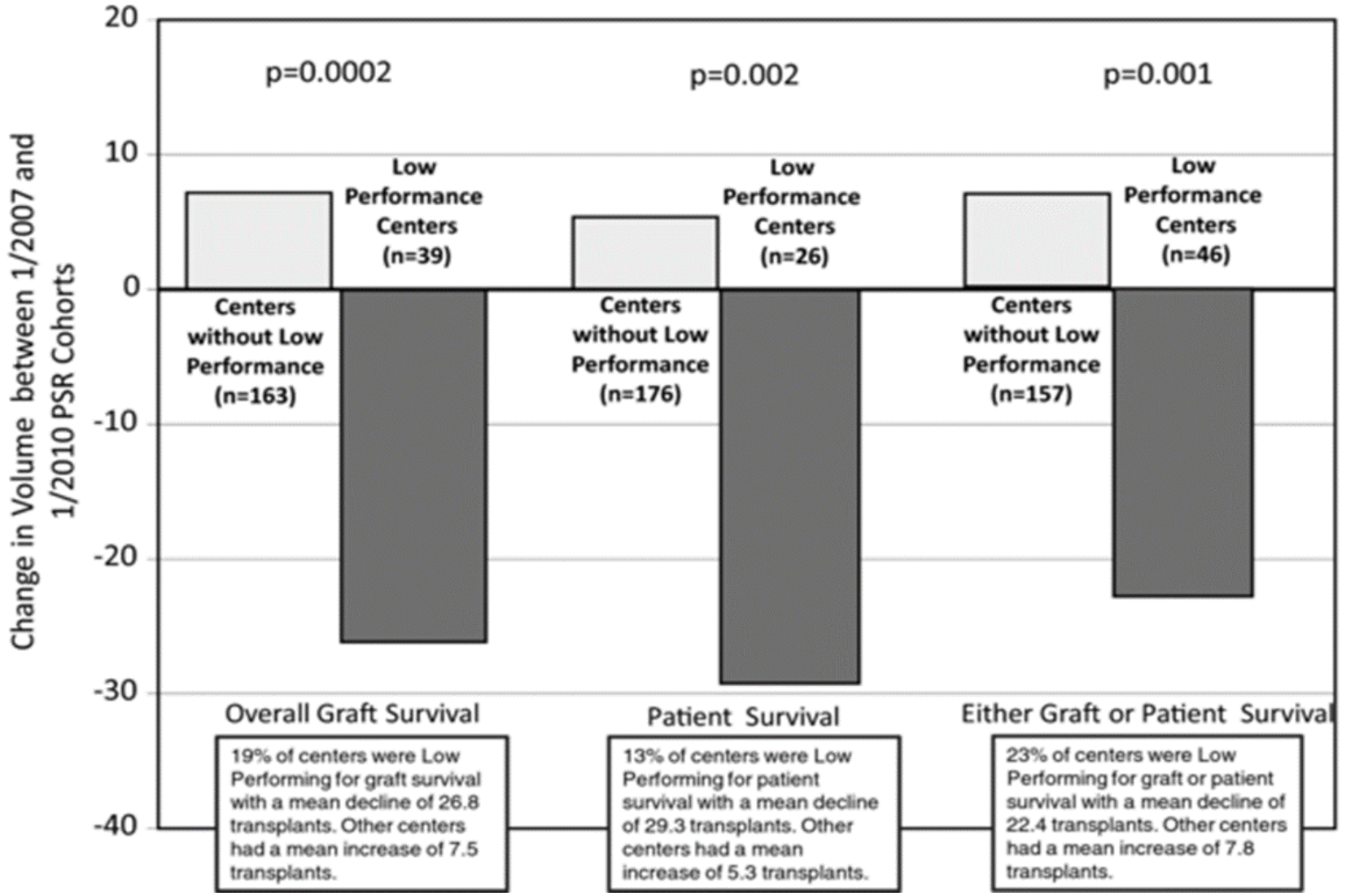
Transplant Volume Declines in Centers Identified as “Low Performing”



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ASTS Recommendations: Eliminate Disincentives

- **Eliminate outcomes-related "star ratings"** and institute a process to engage patient organizations to reform Program Specific Reports to provide data most useful to patients in a user-friendly format.
- **Eliminate current outcomes-based flagging** criteria used to trigger OPTN/MPSC performance reviews for each organ type. **Substitute "Minimum Outcomes Performance Levels"** with sufficient leeway to facilitate more liberal organ acceptance practices.
- **Establish a process** for the transplant community to work with officials from HRSA and CMS jointly to encourage increased acceptance of organs at risk of discard while ensuring that transplant surgeons retain the flexibility to make organ acceptance decisions based on their patients' best interests.

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ASTS Recommendations: Other Areas Requiring Increased Focus and Coordination

- OPO CFCs encourage use of organs at risk of discard.
  - *Current organ allocation methodology prioritizes waitlist time, sickness, immunologic factors and these patients may not be the appropriate recipients for organs at risk of discard.*
- CMMI demonstrations and CMS quality incentives for dialysis centers encourage nephrologists and dialysis centers to get their patients waitlisted.
  - *"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.
  - *CMS cost accounting rules disincentivize Transplant Centers from using Organ Recovery Centers to recover organs.*

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The Longer-Term Challenge: Closer Coordination of Transplant-Related Issues within HHS

- These initiatives requires increased coordination among:
  - All agencies within HHS, including various components of CMS, HRSA, and HRSA contractors (OPTN and SRTR)
  - Organizations representing the transplant community including ASTS
  - Dialysis centers
  - OPOs
  - Donor Hospitals and
  - Patient organizations

- We encourage the establishment of formal and informal mechanisms to better coordinate efforts in the interest of our patients.

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Thank You

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Attachment C

ASTS Letter to HRSA Acting Administrator Diana Espinosa, February 2021

American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

February 2, 2021

Diana Espinosa, MPP
Acting Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane, Rm 13N138
Rockville, MD 20857

Dear Administrator Espinosa:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to follow up on a meeting held on February 7, 2020 with HRSA Administrator Tom Engels and other HRSA staff regarding the disincentives to transplantation that result from outcomes metrics currently used by the Organ Procurement and Transplantation Network (OPTN) in evaluating Transplant Center (TC) performance and TC outcomes-related "star ratings" calculated by the Scientific Registry of Transplant Recipients (SRTR). While we recognize and appreciate the pressing need for HRSA to focus on addressing the public health crisis created by COVID-19, we believe that the need to address these disincentives also requires immediate attention, in light of new regulations recently finalized by the Centers for Medicare and Medicaid Services (CMS) that create equally strong incentives for the nation's Organ Procurement Organizations (OPOs) to increase transplant rates.

We strongly believe that close coordination between HRSA's Division of Transplantation and CMS' Center for Clinical Standards and Quality (CCSQ) is necessary to address this conflict between CMS' OPO certification standards and the TC performance metrics used by the OPTN and SRTR. For this reason, we request a joint meeting involving the ASTS, HRSA, and CMS to address this issue. A similar request has been submitted to Dr. Fleisher, the Director of CCSQ. We are aware that the OPTN Membership and Professional Standards Committee (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.

The rationale and supporting data for our request are set forth in the attached document entitled **"The Need to Reconcile OPO Conditions for Coverage and OPTN/SRTR Outcomes Metrics"** (see Attachment A) and related attachments. Please note that, based on this data, 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 also attached (see Attachment B).

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

We look forward to hearing from you regarding the availability of you and your staff for such a joint meeting. If you have any questions, please do not hesitate to contact ASTS Executive Director Maggie Kebler-Bullock at Maggie.Kebler@asts.org or on (703) 414-7870.

Sincerely yours,

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

Cc. Cheryl R. Dammons, Associate Administrator, Healthcare Systems Bureau, HRSA
Frank Holloman, Director, Division of Transplantation, HSB, HRSA
Lee Fleisher, MD, Chief Medical Officer & Dir., Center for Clinical Standards & Quality (CCSQ)
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

Attachment A

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 C.

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 risker. 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.

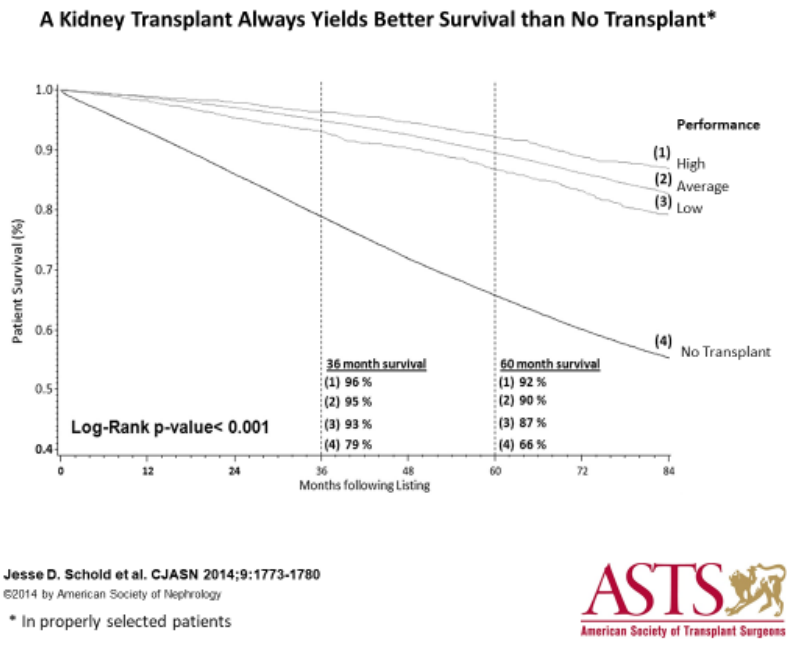
To put this issue in context, it is critical to note that, based on 2016 data, receiving a transplant at a highly underperforming center still greatly improves survival when compared with remaining on the waiting list for end-stage renal disease patients.

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



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

* In properly selected patients

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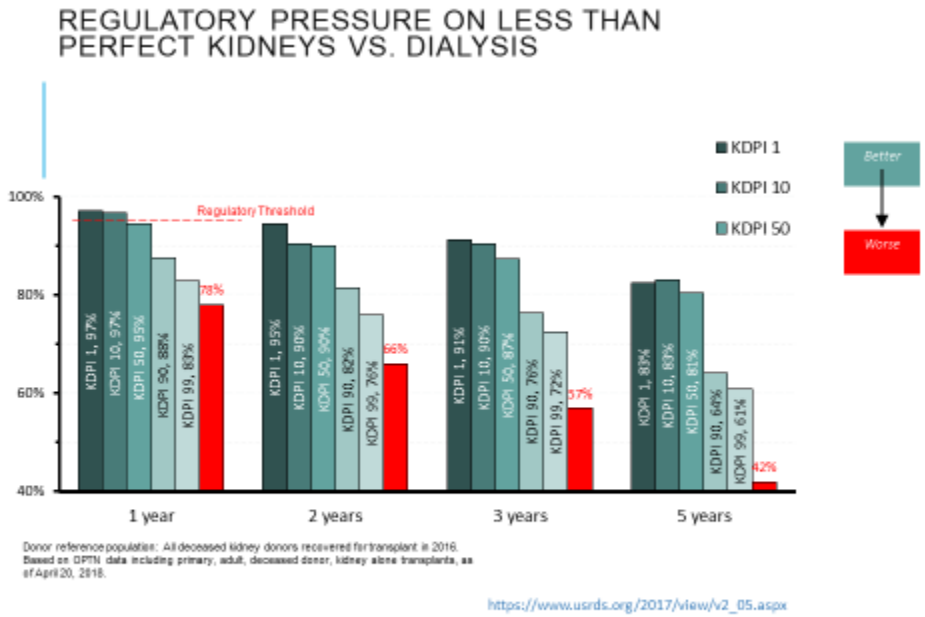
In addition, USRDS data shows the disincentive to use marginal (higher KDPI) kidneys, in an effort to maintain the mandated regulatory transplant success rates. The outcome rates for remaining on dialysis are contrasted as well. Even the most marginal kidneys have better outcomes than remaining on dialysis.



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

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 Program-Specific Report (PSR), which is made publicly available and is used by both patients to determine where to get waitlisted[1] 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.[2] Because of increasingly positive one-year outcomes for kidney transplantation overall, TC's star rating can fall significantly with only one or two adverse outcomes.

[1]Schaffhausen, 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).

[2]Snyder 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]

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

1-Year kidney Survival (% with functioning transplant at 1 year)	**93**	**94**	**96**	**97**	**98**

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.[3] In addition, lower star ratings are not associated with eventual post-transplant outcomes in either kidney or heart transplantation.[4] Yet, a survey of transplant programs established that over half of programs whose star 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.[5]

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.[6] 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

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[3]Jesse 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.

[4]Wey, 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.

[5]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.

[6]Farid 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.

2017 article published by Drs. Jay and Schold, *Measuring transplant center performance: The goals are not controversial but the methods and consequences can be,*[7] 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.[8]

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.

[7]Jay, 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.

[8]J.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.

Attachment B

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.[9] 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.[10] 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.

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

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[9]Buccini 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.

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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.

[10]Bowring 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.

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.[11] *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.

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

[11]Bowring 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.

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." [12]

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."

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."

[12] https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf

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.[13] ASTS believes that OPTN/MPSC processes should further this goal by modifying the current outcomes-based methodology for triggering MPSC performance review and substituting a confidential peer review process

[13] https://optn.transplant.hrsa.gov/governance/straegic-plan/goal-1/

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 C

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 D

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Attachment D

ASTS Presentation for Meeting with HRSA Administrator Thomas Engels
February 7, 2020

Request for Elimination of Disincentives for Transplantation Imposed by HRSA Contractors (OPTN and SRTR)

AMERICAN SOCIETY OF TRANSPLANT SURGEONS (ASTS)

FEBRUARY 7, 2020

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The Problem

The Advancing Kidney Health Initiative (KHI) establishes the goal of doubling the number of kidney transplants by 2030.

- One-year post-transplant outcomes requirements:
  - Disincentivize use of imperfect organs,
  - Incentivize conservative patient selection, and
  - Inhibit innovation.
- In October 2019, CMS eliminated one-year outcomes requirements as a condition of Medicare recertification of Transplant Centers

BUT

Two HRSA contractors — the OPTN and SRTR — continue to impose outcomes standards that strongly disincentivize the use of imperfect organs.

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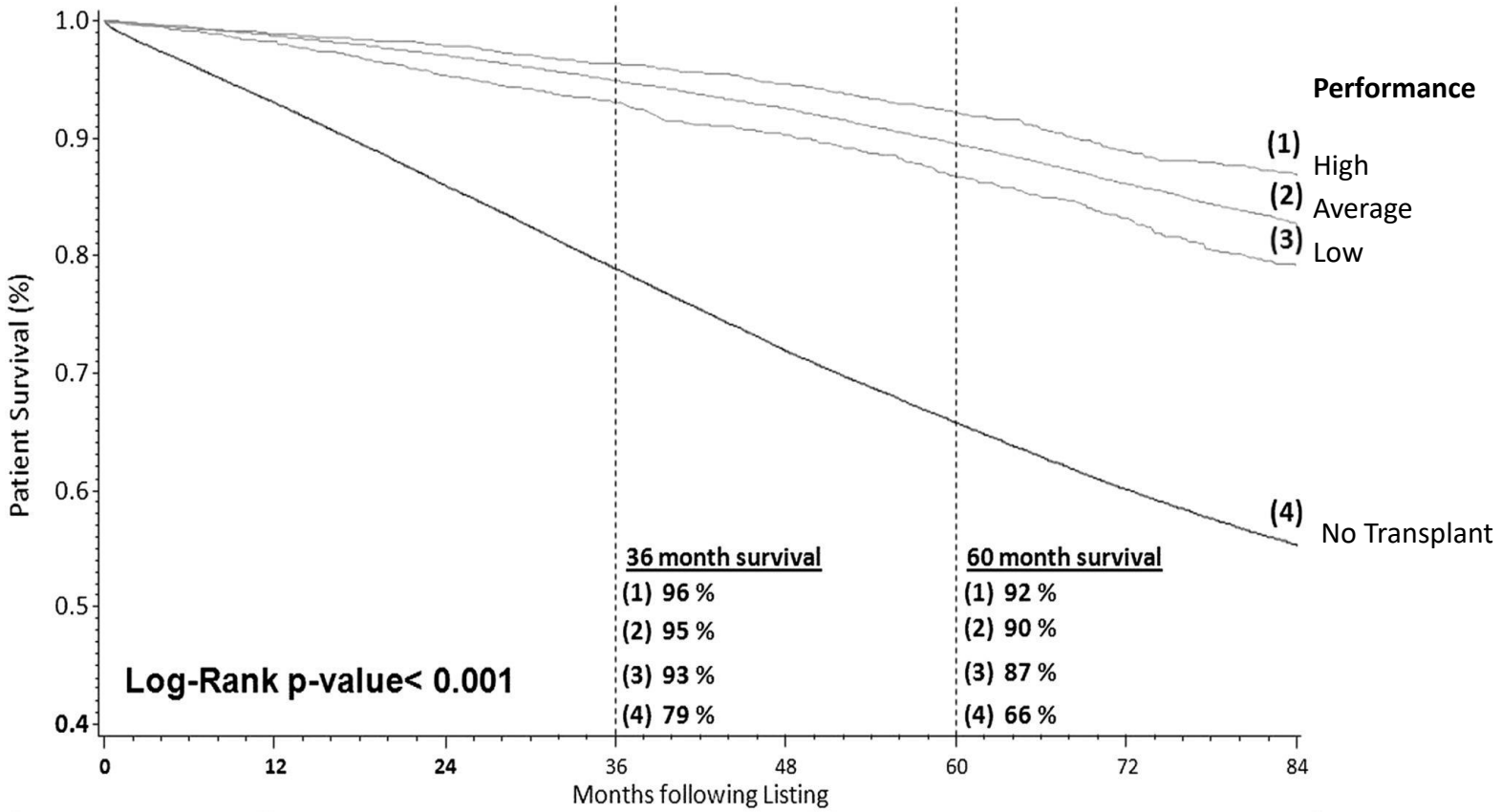
Context

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

* In properly selected patients

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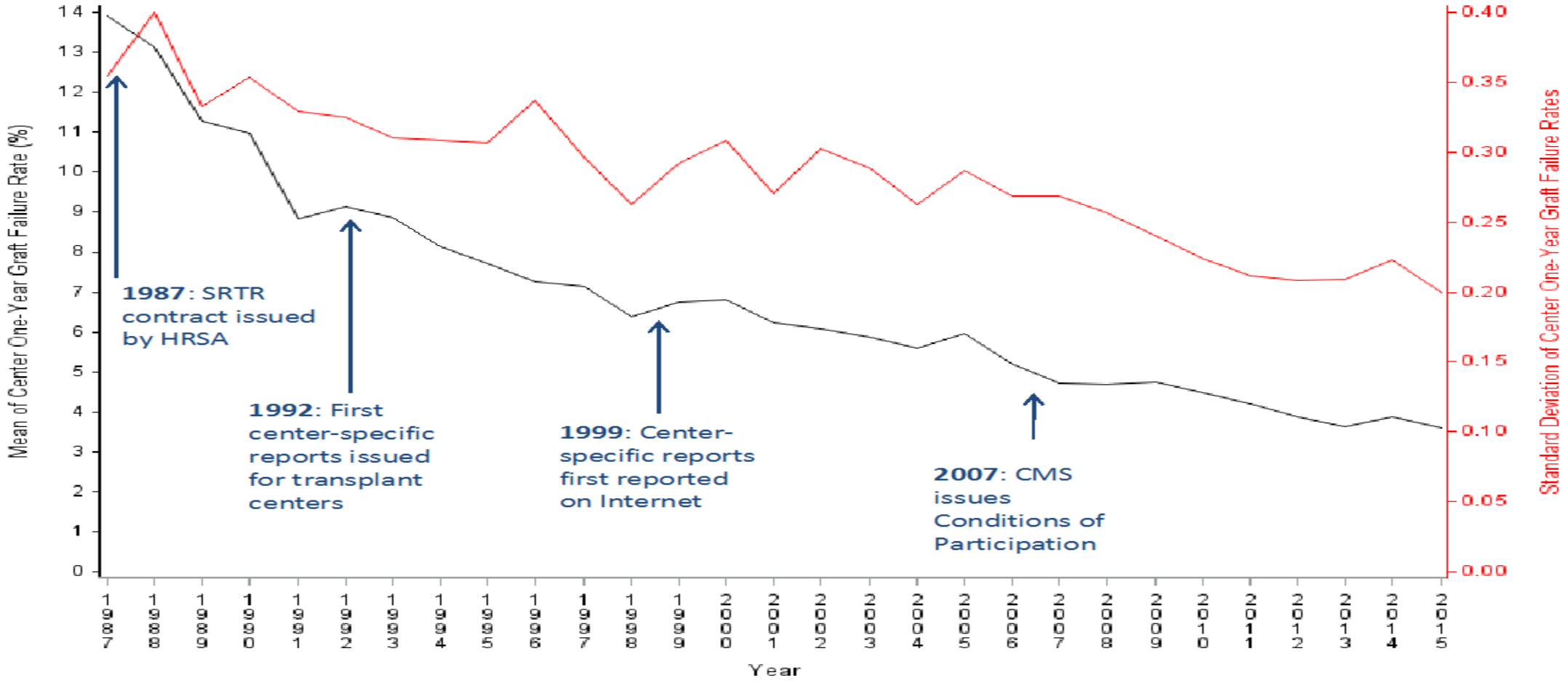
1-Year Kidney Graft Failure Rate (%) among U.S. Transplant Centers: 1987-2015



Weighted mean graft failure rate data from 181 transplant centers in 1987 through 235 centers in 2015

The Problem: OPTN Outcomes Assessment

- NOTA does not include regulation of transplant centers (TCs) as an activity performed by the OPTN.
- While the OPTN has regulatory authority to determine membership criteria, it is **required by regulation** (42 CFR § 121.1(b)) to include as members all Medicare-certified TCs.
- CMS has eliminated outcomes requirements as a condition of TC recertification, but the OPTN continues to impose outcomes requirements as a condition of OPTN membership.
- In fact, OPTN outcomes criteria for TCs are far **stricter** than the prior CMS outcomes requirements.

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The Problem: OPTN Outcomes Assessment is Based Exclusively on Post-Transplant Outcomes

- Exclusive focus on post- transplant outcomes:
  - Fails to take into account access to transplantation.
  - Fails to take into account the transplant “continuum of care.”

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The Problem: OPTN Post-Transplant Outcomes Assessment is Flawed

- Major concerns with OPTN flagging criteria:
  - Transplant Centers (TCs) are flagged based on small differences between center performance and the national (as little as 2% difference) .
  - A significant number of transplant programs are identified as low performing (up to one-third of all TCs at any one time) by the OPTN, despite relatively small survival and clinically insignificant differences compared with expected.
  - The formula is mathematically complex and often difficult to understand.
  - Standards change every reporting period which makes hitting the target difficult.
- Flagging may trigger quasi-legal proceedings potentially resulting in public announcement that a TC is “on probation” or is a “Member Not In Good Standing.”

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The Problem: OPTN Post-Transplant Outcomes Assessment is Flawed

OPTN vs. CMS “Flagging” Criteria:

- OPTN criteria flag significantly more kidney programs than the (now discarded) CMS criteria.
- OPTN criteria flag four times as many low performing small volume centers and three times as many low performing high volume centers as CMS criteria.

Evaluation of Flagging Criteria of United States Kidney Transplant Center Performance: How to Best Define Outliers? Transplantation. 2017

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The Problem: SRTR Star Ratings

- SRTR recently implemented a 5-star system for assessing TCs, based on one-year post –transplant outcomes. **This system is used both by patients and by private payers to determine whether a TC can participate in its network.**

YET:

- Star ratings are confusing to patients
- Lower **star ratings are not associated with eventual post-transplant outcomes** in either kidney or heart transplantation.
- SRTR ratings are highly **volatile.** Based on historical data, almost all centers (94%) fluctuate by at least one star within three years and almost half (46%) fluctuate by at least two stars within three years**.**

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The Problem: SRTR Star Ratings

- New Five-Star rating system yields counterintuitive results.
- As the result of risk adjustment and statistical issues. For example:
  - A TC with a 98% First Year Survival can be rated as a three-star program.
  - A new TC with a 100% First Year Survival can be rated as a four-star program.
  - A TC that is shut down can have a higher star rating than a functioning center.

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Attachment E

ASTS Presentation to HRSA Administrator George Sigounas, May 3, 2018

Request for Relief from Duplicative Regulation of Transplant Centers

AMERICAN SOCIETY OF TRANSPLANT SURGEONS (ASTS)

MAY 3, 2018

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Overview of Presentation

- The Problem
- Historical Background
- The Administrative Burden
- Proposed Solution

The Problem

Both CMS and HRSA (through the OPTN) currently impose extensive regulatory requirements on Transplant Centers (TCs), which are enforced through separate (uncoordinated) surveys and subject to different review (appeals) mechanisms.

- The OPTN imposes extensive requirements on Transplant Centers as a condition of maintaining their OPTN membership.
- Since 2007, CMS has imposed extensive conditions of participation on Transplant Centers, including both outcomes (one year patient and graft survival) and process requirements.

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The Problem *(Cont'd)*

- Altogether, there are over 123 separate requirements, approximately 30% of which are reviewed by both CMS and the OPTN.
- In addition, CMS and OPTN requirements in areas of overlap may be inconsistent, for example:
  - Different requirements with respect to clinical outcomes.
  - Different requirements with respect to clinical experience (i.e. case volume requirements)
- Both sets of requirements are overly prescriptive and interfere with the patient-physician relationship.

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The Problem *(Cont'd)*

- Generally, these extensive requirements relate to the process of care used by TCs.
- The extensive application of process requirements is particularly inappropriate in light of the demanding OUTCOMES requirements that both HRSA and CMS impose on TCs, which closely examine one year survival of transplant recipients and organs on a continuous basis.

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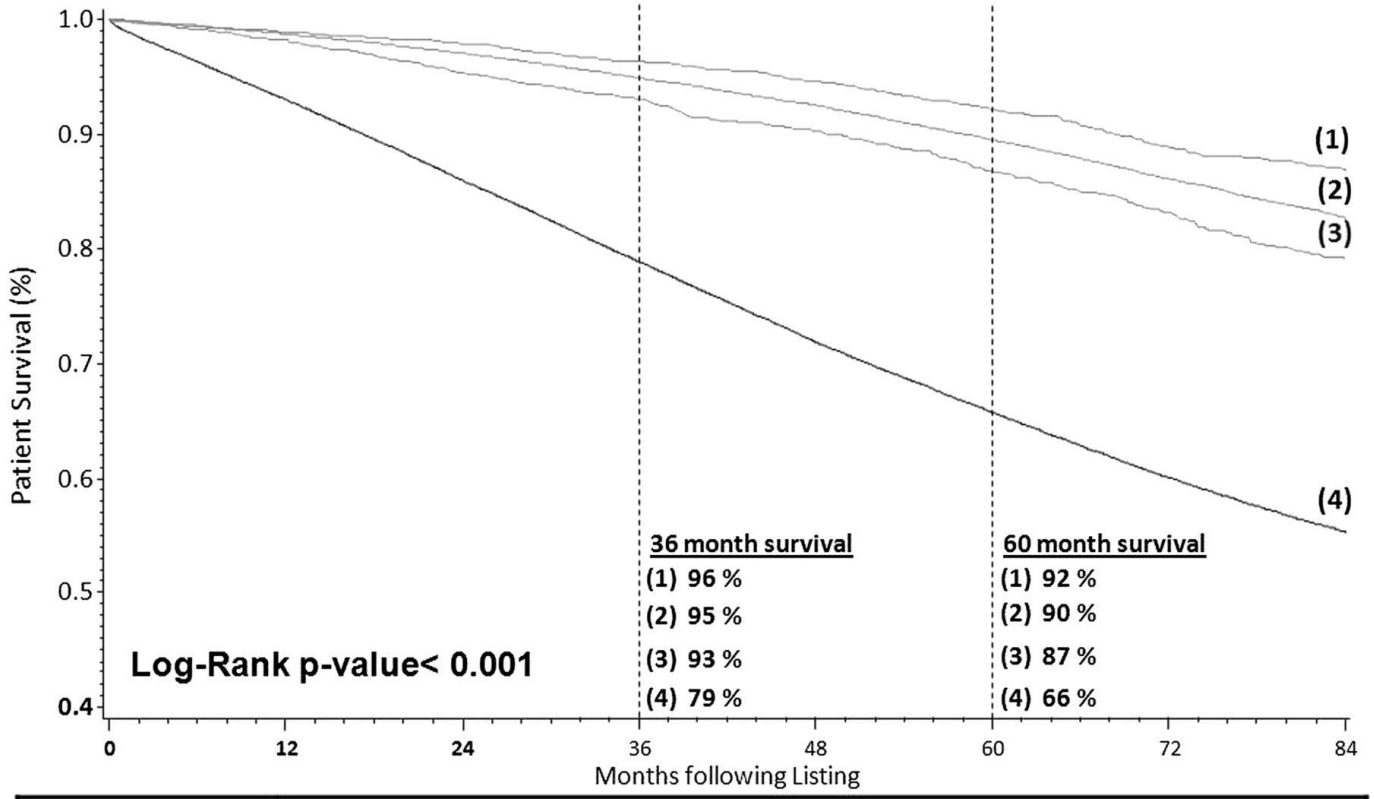
Context

Patient survival after listing by transplant status and center quality on the basis of deceased donor transplantation at a transplant center with a given performance at the time of listing.



Study Group	Numbers at risk			
	12 months	36 months	60 months	84 months
(1) Tx atHigh Performers	3211	2201	1586	443
(2) Tx at Average Performers	63191	44725	26661	9683
(3) Tx at Low Performers	2585	1907	1230	482
(4) No Transplant	118508	61751	27224	8219

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

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Historical Background

The OPTN was created by the National Organ Transplantation Act, enacted in 1984, and OPTN provisions were proposed in 1986.

NOTA specifically enumerates the tasks that the OPTN is authorized to perform. There is no "catch all" provision that allows the OPTN to perform tasks that are NOT enumerated in the statute.

NONE of the OPTN's statutory responsibilities provide authority for it to engage in ongoing regulation of transplant centers.

- In fact, none of the OPTN's specific tasks under NOTA extend to transplantation: Rather, the OPTN's statutory charge relates to organ acquisition, distribution, and transportation.

- The ONLY provision that even suggests OPTN authority over transplant centers is a general provision that authorizes the OPTN to establish membership criteria, and transplant centers are members of the OPTN.

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Historical Background

The regulations that implement NOTA provide, in relevant part:

> (*b) Membership of the OPTN.*
>
> *(1) The OPTN **shall** admit and retain as members the following: . . .*
>
> *(ii) Transplant hospitals participating in the Medicare or Medicaid programs;*

(42 CFR § 121.1(b) (Emphasis added.)

Implications:

- The Final OPTN Rule does **NOT** anticipate duplicative regulation of TCs by both CMS and the OPTN.
- The OPTN does not have regulatory authority to terminate the membership of a TC that meets Medicare Conditions of Participation.

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Historical Background

However, when the OPTN was established, membership criteria were needed for transplant centers.

- OPTN established basic criteria for membership, related primarily to the qualifications and experience requirements for transplant surgeons and other members of the transplant team.

CMS did not adopt and implement final Conditions of Participation (CoPs) for transplant centers until **June 2007**.

- The CoPs include extensive outcome and process requirements.
- The CoPs also include a provision that requires OPTN membership as a condition of Medicare participation.

SO…

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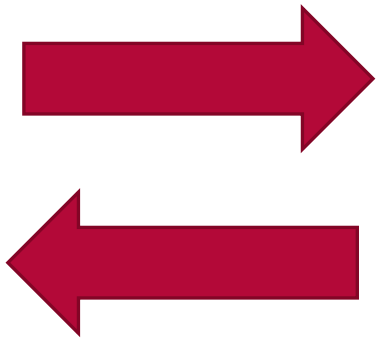
Historical Background

Thus….

CMS requires TCs to be members of OPTN to be Medicare certified



OPTN regulation provides that all MC-certified TCs are qualified to be OPTN members.

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EXAMPLES OF DUPLICATIVE REGULATION

OPTN regulatory requirements include:

- 230 pages of policy,
- 180 pages of Bylaws
- 65 pages of Evaluation Plan.

CMS regulatory requirements include:

- 85 pages of the Federal Register,
- 107 pages of Survey and Certification Interpretive Guidelines,
- 50 pages of Survey and Certification Interpretive Changes,
- 49 pages of Quality Assessment and Performance Improvement (QAPI) Program requirements,
- Numerous additional updates and clarifications.

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EXAMPLES (cont'd)

Organ and Vessel Tracking

Patient Education and Consent

Time Requirements & Disparate Survey Timeframes

Clinical Micromanagement

ABO verification

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All of this--with little or no specific statutory authority

- OPTN rules rest solely on its authority to establish membership criteria.
- CMS authority rests primarily on its authority to ensure that Medicare only pays for “reasonable and necessary” services.

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Our Proposal: Reform Principles

- **One set of TC oversight regulations** and regulatory interpretation;
- **One set of TC outcomes measures** intended to maximize transplantation rates;
- **One combined survey** conducted as necessary based on a single set of survey triggers; and
- **One set of consequences** for noncompliance.

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Operationalizing Reform

These Principles could be operationalized in a number of ways.

However, each of the two agencies has considerable expertise and resources that the other does not.

Our proposal seeks to ensure that these areas of expertise are not lost.

Operationalizing Reform

- Approval of New TCs for OPTN Membership – OPTN
- Organ Retrieval and Allocation, Waitlist Management, and Related Data Management – OPTN
  - Any necessary survey activity to be conducted as part of unified OPTN-HRSA/CMS survey.
- All other regulatory requirements to be reviewed and revised to comply with the Reform Principles by an Interagency Committee or Task Force.

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Operationalizing Reform

INTERAGENCY COMMITTEE TASKS:

ONE SET OF OUTCOMES REQUIREMENTS

- Interagency Task Force should establish one unified set of outcomes standards.
- Consult with affected community to ensure that outcomes standards do not dissuade the use of non-standard organs.

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Operationalizing Reform

INTERAGENCY COMMITTEE TASKS :

ONE SET OF IMPLEMENTING REGULATIONS

- Streamline or Eliminate Process Requirements to Focus on Transparency and Due Process
- So long as a TC is in compliance with outcomes standards, detailed process requirements related to clinical matters are unnecessary.
- Process requirements should focus on matters generally unrelated to clinical issues:
  - Patient rights
  - Core safety measures
  - QAPI programs
  - Care of living donors

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Operationalizing Reform

INTERAGENCY COMMITTEE TASKS:

ONE SET OF GUIDELINES

- Guidelines should minimize administrative burden and should be limited to patient rights, safety, QAPI, and care of living donors.
- Developed with input from the transplant community.
- If there is a conflict between CMS and OPTN, follow least prescriptive guideline.
- To the extent that TCs are expected to utilize a particular form or process, a model document should be provided to the transplant community.

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Operationalizing Reform

INTERAGENCY COMMITTEE TASKS:

ONE UNIFIED SURVEY

Establish the procedures for conducting joint oversight surveys.

- Performed by surveyors from both CMS and OPTN, working together.
- On-site surveys limited to well-defined circumstances, e.g.
  - Failure to meet outcomes standards.
  - Major sentinel events
  - Failure to comply with OPTN rules regarding listing and allocation practices

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Operationalizing Reform

INTERAGENCY COMMITTEE TASKS :

ONE SET OF CONSEQUENCES

- Merge OPTN and CMS plan of corrections/mitigating circumstances processes.
- Establish process for joint OPTN/SRTR and CMS review of TC performance that does not comply that draws upon the expertise of the OPTN's Membership and Professional Standards Committee.

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Conclusions

- Transplant center regulation is an over-regulation "poster child."
- Focus on de-regulation and elimination of duplicative oversight has the potential to significantly benefit patients and the Medicare Program by making transplantation more accessible and less costly.

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Attachment F

Letter to Daniel Schwartz, MD and James Cowher, CDR, USPHS
June 25, 2019

American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

Via E-Mail

June 25, 2019

Daniel Schwartz, MD, MBA
Physician
Quality, Safety & Oversight Group (QSOG)
CCSQ/CMS
7500 Security Boulevard
Mail Stop: C2-21-16
Baltimore, MD 21244

James Cowher, CDR, USPHS
Division Director (Acting)
Division of Continuing Care Providers
Quality, Safety & Oversight Group; C2-18-03
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Schwartz and Mr. Cowher:

On behalf of the American Society of Transplant Surgeons (ASTS), I am writing to follow up on our call of June 18 regarding the new Interpretive Guidelines ("IGs") for Transplant Centers. As we discussed, while we applaud CMS' efforts to simplify and streamline the IGs, a number of the provisions of the new IGs have raised concerns among ASTS members. We very much appreciate the time that you spent discussing these concerns with us and your openness to considering our views on these important issues.

We thought that it might be useful for us to provide to you proposed modifications of the IG language that we believe would alleviate our members' concerns in a manner that is consistent with CMS' views, as expressed during our call. Our suggested modifications of the IG language are provided on Attachment A. Language proposed for deletion is ~~stricken~~ and new proposed language is in *italic* typeface. We hope that these suggestions accurately reflect our discussions with you and are consistent with CMS' interpretations of the governing regulations.

Implementation of the IG provisions of concern would require Transplant Centers to institute substantial operational changes. For example, the requirement for Independent Living Donor Advocate (ILDA) pre-evaluation interviews with potential living donors has the potential to significantly disrupt the current work flow for living donor teams; the

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ASTS.org

provision precluding any ILDA involvement with transplant activities implicates ILDA staffing; and the requirement for “skin-to-skin” supervision of fellows and residents would interfere with current teaching practices. For this reason, we request that CMS direct state survey agencies to suspend enforcement of the IGs that we have discussed pending consideration of ASTS’ concerns and that we plan to meet again by phone in two weeks to discuss the status of these IGs.

We look forward to working with you to address other issues that may arise with regard to the new IGs and the new transplant center certification process and hope that we can be of assistance in facilitating communication between CMS and the transplant community. If you have any questions or if we can be of any further assistance, please do not hesitate to contact ASTS Advocacy Manager Jennifer Nelson-Dowdy at Jennifer.Nelson-Dowdy@asts.org.

Sincerely yours,

Lloyd E. Ratner, MD, MPH
ASTS President

Cc: Valerie Caldwell-Johnson, Transplant Team

Attachment A

Direct Supervision by Transplant Surgeon

Applicable Regulation:

The Transplant Center (TC) certification regulations provide that the Transplant Director is responsible for, among other things:

> Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).[1]

42 CFR §482.98(a)(3).

Interpretive Guideline Suggested Change:

> If a fellow or a resident participates in a surgery, the attending transplant surgeon must remain in the operating room or be physically present in the operating suite *to the same extent as required for other teaching physicians in the hospital*. *Generally, this requires that the attending surgeon be present for the key/critical portions of the surgical procedure*.

Rationale:

We understand that CMS' intent is to ensure that the same supervision requirements are applied for transplantation as for other surgical specialties. Medicare payment rules applicable to teaching physicians as well as the standard definition of direct supervision in the surgical context – which has been accepted by CMS--requires that the supervising physician be present during the key/critical portions of the surgical procedure.

[1] Section 482.98(b) does not provide any definition of direct supervision, but rather requires only that a primary transplant surgeon have the appropriate training and experience to provide transplant services and that s/he be immediately available to provide transplant services when an organ is offered for transplantation.

Independent Living Donor Advocate (ILDA) Independence

Applicable Regulation:

The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

42 CFR §482.98(d)(1)

IG Suggested Change:

> Because of the conflict of interest which would be created for an advocate to perform ~~any~~ transplant activities *other than those related to the ILDA role on a routine basis*, ~~even on an infrequent basis~~, the ILDA or ILDAT must not ~~be associated with the transplant program in any capacity even on a temporary or intermittent~~ *routinely engage in transplant-related activities other than those related to carrying out the responsibilities described at §482.98(d)(3) and accompanying Tags. Interview the ILDA or ILDAT to ensure that ILDA activities are focused exclusively on representing and advising the donor; protecting and promoting the interests of the donor; and respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion. In particular, ensure that the ILDA or an ILDA team member does not also serve as a member of a transplant recipient team.*

Rationale:

ASTS completely agrees that an ILDA and all ILDA team members must be free of conflict of interest and that this function should not be performed by those who also routinely serve on transplant recipient teams. At the same time, it is critical that the ILDA function be performed by trained individuals with substantial knowledge of the transplant procedure, process, benefits, and risks. Such knowledge cannot be obtained without substantial and ongoing association with the transplant team. We believe that precluding an ILDA (or ILDAT member) from routinely performing transplant-related activities other than those that advance the interests of living donors is consistent with the regulatory language and strikes an appropriate balance between the need for independence and the need for ILDAs to be trained professionals with significant knowledge of the transplant process.

Living Donor Pre-Evaluation ILDA Interview and Other Living Donor Pre-Evaluation Requirements

Applicable Regulation:

Standard: Independent Living Donor Advocate or Living Donor Advocate Team. The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

42 CFR §482.98(d)

§482.98(d) IG Suggested Change:

> Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) ~~prior to the initiation of the~~ *during the* evaluation *phase* and continuing to and through the discharge phase.

Standard Transplant Center Survey Protocol Suggested Change (Task 4.V):

> 'The medical record must include evidence that the Independent Living Donor Advocate (ILDA) was made available to the living donor, to include the name and contact information of the ILDA. Every living donor must be assigned and have an interview with the ILDA or ILDA team ~~prior to the initiation of~~ *during the* evaluation *phase* and throughout the donation phase."

***

Applicable Regulation:

Standard: Informed consent for living donors.

> Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following

***

> (2) The evaluation process;

***

> (5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available.

IG Suggested Changes:

Guideline §482.102(b)(2)

The informed consent process ensures that the donor understands what the evaluation process entails ~~prior to its initiation~~. ~~Prior to~~ *When* a donor candidate ~~making~~ *makes* a decision to ~~undergo~~ *proceed with* an evaluation for donation, they must understand what the process demands, patient and transplant program responsibilities, what determination(s) can be made as the result of an evaluation, and what factors could determine their non-candidacy for donation. The evaluation process is ongoing, beginning at the time ~~an individual is identified as a possible candidate~~ *of the evaluation for* donation and continues until donation. Routine re-assessments, as determined by the program's protocols must be conducted to ensure continued suitability for donation

Guideline §482.102(b)(5)

There are general risks applicable to all organ transplants and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential donor ~~*prior to his/her decision to proceed with*~~ *during* the evaluation process. The informed consent discussion should include information regarding the fact that long term medical implications of organ donation have not been fully identified.

Guideline §482.102(b)(6)

~~Prior to undergoing~~ *During* an evaluation, the transplant program informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential ~~recipient~~ *donor* should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. There are currently no national or center specific outcomes for living donors calculated by the SRTR.

Applicable Regulation:

If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation

42 CFR §482.94

IG Suggested Change:

Guideline §482.94

Living Donor Care Phases:

• Evaluation Phase: *Begins at the potential donor's first visit to the Transplant Center following any preliminary blood, tissue or similar screening and ends at* ~~from first presentation by the potential donor~~ the time he/she enters the OR for the donation surgery.

Rationale:

As indicated during our call, it is standard procedure for potential living donors to undergo rudimentary screening before the decision is made about whether or not to schedule evaluation. Potential living donors may reside great distances away from potential recipients, and the requirements for a pre-evaluation interview with an ILDA and the other pre-evaluation requirements imposed by the new IGs have the potential to substantially delay the living donor matching process and result in unnecessary inconvenience and expense for living donors. In addition, as the result of screening, many potential donors are essentially eliminated from consideration, and the imposition of pre-evaluation requirements of the kind reflected in the new IGs has the potential to result in substantial loss of time and increase in expenditures for Transplant Centers—expenses that are ultimately paid by the Medicare program, which provides cost-based payment for organ acquisition costs. Finally, the governing regulations do not recognize a "Pre-evaluation" phase for living donors.

Transplant Director Responsibilities

Applicable Regulation:

§482.98(a) Standard: Director of a Transplant Center.

> The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. . . The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:
>
> 1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

IG Suggested Change:

> **Guideline §482.98(a)(1)**
>
> **.** .. . Evidence of coordination should include:
>
> 1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors; *and*
>
> 2. The transplant director offers ongoing training opportunities for nursing staff. ~~; and~~
>
> ~~3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors~~

Rationale:

In some institutions, nursing staff may be employed by a different entity or Human Resources rules lines may preclude a Transplant Director from providing direct input on nursing staff. In addition, this provision of the IG appears to be outside the scope of the governing regulation, which only addresses the Transplant Director's responsibility with regard to training and orientation for nursing staff working with transplant recipients and living donors.

Attachment G

ASTS Response to the UNOS Proposal
Enhance Transplant Program Performance Monitoring System
September 30, 2021

The American Society of Transplant Surgeons (ASTS) strongly opposes this policy proposal as written. ASTS applauds the OPTN for its initiative in its undertaking to revise the metrics used by the MPSC for performance review. The ASTS also believes that such efforts should be collaborative and in cooperation with UNOS and other transplant organizations - with the goal of improving patient outcomes. Regulatory metrics are complex and have significant unintended consequences. For example, it is well recognized that the current MPSC one-year outcome metrics, along with the SRTR five-star public ratings, do not allow patients to achieve optimal transplant opportunities as they strongly disincentivize transplant programs from accepting organs at risk of discard and from transplanting older and medically complex recipients. The available clinical literature strongly supports that transplant programs that are flagged by the MPSC for performance review curtail transplantation. In light of the large number of potential transplant recipients who die awaiting a life-saving transplant, it is clear that the OPTN's mission of enhancing patient safety is best served by eliminating disincentives to transplantation created in part by the transplant program monitoring processes, including disincentives created by the current MPSC outcomes-based triggers for performance review.

In addition, the newly proposed MPSC performance review criteria do not further the cause of patient safety as both wait list mortality and organ acceptance rates depend on multiple geographic, clinical and organ distribution issues that are not captured by current data. Importantly, the proposed MPSC performance review criteria do not appear to improve quality, increase the number of transplants, or promote innovation.

The proposed revised metrics have the potential to increase, rather than reduce, risk aversive patient and organ selection and to reduce, rather than increase, the number of clinically appropriate transplants performed. Specifically, the addition of waitlist mortality to the metrics that trigger performance review has the potential to incentivize exclusion of sicker patients and those with lower socio-economic status from transplant program waiting lists. The inclusion of an organ acceptance metric as a trigger for performance review has the potential to encourage transplant programs to narrow their organ acceptance criteria to avoid being flagged—that is, to narrow the organs that it will be offered in order to avoid review based on the organ acceptance metric. This will ultimately result in fewer transplants, more waitlist deaths, and increased rather than decreased organ discards. In our view, the current proposal does not address the critical flaw inherent in the current flagging criteria (i.e. the criteria's reinforcement of risk averse recipient and organ selection) and applying these multiple regulatory metrics concomitantly has the potential to exacerbate current transplant program risk aversion decreasing transplants for patients in the U.S.

We urge the OPTN to adopt a focused approach to transplant program oversight that has a single goal: To increase the availability of clinically appropriate transplantation while maintaining or improving quality. Our suggested approach is comprised of two components:

- Reform the current outcomes metrics to establish a tiered risk-adjusted pass/fail system under which the "pass rate" is established in a manner that ensures a defined excellent outcome and a patient benefit of transplantation as compared with the available clinical alternatives (e.g. dialysis, in the case of renal transplants) rather than an "expected" survival rate which is unpredictable and has increased each year due to centers' increasingly risk averse patient and graft selection from the prior years.
- Implement Systems and Quality Improvement Projects that focus on improving access to transplantation through non-punitive pilot programs.

A. Patient-Centered Outcomes Metric

Any effort to reform the MPSC's oversight of transplant programs should begin with reform of outcome metrics that are currently used to trigger performance review. For the reasons set forth in the *ASTS Recommendations for the Optimization of Transplant Center Assessment* (January 12, 2021 (See #1 in References), we urge the OPTN to establish an easily understood binary (pass/fail) metric under which a transplant program's "pass rate" is established by reference to national annually predetermined excellent outcomes that are pinned to the available clinical alternatives. For example, based on SRTR data, the mean age of a renal transplant recipient at time of transplant is approximately *58 years* old and that the mean renal transplant recipient has been on dialysis for *3.5 years* at the time of transplant. Assume further that the one-year patient survival for patients in this age cohort who have just begun dialysis is 89% (USRDS data). Under these circumstances, a renal transplant program that exceeds this benchmark would not be flagged for MPSC review. This basic concept could be further refined to ensure that chosen survival rates are high enough to protect patient safety and justify the risk and cost of transplantation.

In its deliberations and its policy proposal, the OPTN rejected this approach on the grounds that it is not risk adjusted and will increase, rather than decrease risk aversion. We believe that if the "pass/fail" rate is determined in the manner suggested—as a straightforward fixed level of performance—it will provide transplant programs with the predictability necessary for them to increase the level of risk that they will accept. We believe that, for example, establishing the pass/fail threshold at or above 90% graft/patient survival would significantly increase the level of risk that programs would be willing to accept. Moreover, risk adjustment could also be included in the system in a number of ways. Risk adjusted outcomes could be used, if necessary, in a secondary analysis. The initial pass-fail determination could be made without risk adjustment and full risk adjustment could be applied to those transplant centers that do not meet the organ or patient survival pass-fail threshold to determine whether that center's performance would meet the risk-adjusted threshold. Centers would need to fail to meet both the unadjusted pass/fail threshold and the risk adjusted expected outcome threshold to undergo MPSC performance review. Thus, this system will establish easy to understand thresholds as well as provide risk adjustment analysis as needed to encourage transplantation in our country.

We urge the OPTN to make this change to the outcomes metrics as a first step on a trial basis and in conjunction with the elimination of the SRTR created PSR "star ratings" to assess whether, and to what extent, transplant programs respond to improvements in more appropriately selective regulatory enforcement.

We believe that increased transplantation resulting from the elimination of disincentives to transplantation may increase access to transplantation in a manner that modifies waitlist mortality and impacts organ acceptance practices, so that imposing additional metrics relating to these areas may be unnecessary. Any further modification of the MPSC flagging metrics that may be necessary to further encourage clinically appropriate transplantation could be implemented in a step-wise fashion to avoid a dramatic increase in risk-averse behavior and a subsequent restriction in access to transplant for patients.

Systems and Quality Improvement Projects

We believe that adoption of patient-centric outcomes metrics should be accompanied by the initiation of Systems and Quality Improvement Projects that likewise focus on increasing the availability of transplantation.

Additional Systems and Quality Improvement Projects focused on increasing the availability of transplantation might include, for example:

- A project that excludes from any outcomes-related MPSC metric (but not data submission requirements) transplants performed under research protocols approved by the MPSC, so long as outcomes data is submitted to the OPTN for study purposes.
- A project that excludes from any outcomes-related MPSC metric (but not data submission requirements) transplants of certain organs at particularly significant risk of discard (as defined by the OPTN, so long as outcomes data is submitted to the OPTN for study purposes).
- A project that increases the flexibility of transplant programs to accept organs at risk of discard (as defined by the OPTN based on current discard data) for pre-identified recipients on the match run, regardless of that potential recipient's place on the waiting list.

We look forward to working with the OPTN on these and other avenues to improve the availability while maintaining the quality of organ transplantation, and we urge the OPTN to adopt our proposed approach to transplant program oversight to further this goal.

B. Direct Response to Current Proposed Metric Changes: Flagging Thresholds

Regardless of whether or not the OPTN adopts the alternative approach to MPSC performance review described above, we strongly urge the OPTN to modify its flagging thresholds to appropriately reduce the number of transplant programs that needlessly undergo performance review. This change is critical to reduce the disincentive to transplantation created by the current performance review process. It is well documented in publications that transplant programs become considerably more risk averse after having been flagged. Reducing the number of programs flagged has the potential to reduce the risk aversion of transplant programs as a whole with no documented risk to patient safety.

It appears clear that the current flagging criteria are over inclusive. Approximately one third of unique transplant programs are flagged every three years, and an average of 10-12% are flagged every six-month review cycle (see #2 in references). Yet very few programs flagged for outcome queries have ever been shown to have true patient safety concerns. This level of regulatory oversight has made the fear of flagging pervasive and has contributed significantly to risk averse

patient and organ selection by transplant programs while delivering no well documented benefit to patient safety.

For this reason, regardless of what metrics are used, we believe that no more than 2.5% of programs should be flagged as being in the Red Flag zone for any solid organ for each PSR. This approach more accurately targets true outliers and has the potential to substantially reduce risk averse behavior by transplant programs. The currently proposed Red Flag zone criteria were set with an eye on not exceeding the number of currently flagged programs in the U.S. While maintaining adequate oversight is important in attempting to maintain a certain number of flagged programs, it appears somewhat random and not scientific.

It is our understanding that the purpose of MPSC performance review is to ensure patient safety. The ASTS believes that ensuring patient safety should be a priority to all those working in the field and that peer review and oversight are important elements of ensuring patient safety. In light of the positive safety profile of transplantation as a whole, MPSC performance reviews should be relatively infrequent. There is no body of published data that supports improved patient safety due to the current large number of U.S. transplant programs undergoing MPSC performance reviews. There is published data, however, showing the negative consequences of the large number of MPSC performance reviews – fewer transplants to U.S. patients and therefore harm to U.S. patients.

Summary

Summarizing, we would strongly urge the OPTN to adopt a simplified proposal which includes a fixed 1-year post transplant patient survival metric. The bar for expected survival should be determined on expected patient survival with the alternative therapy when available (dialysis, or LVAD survival or other best medical management) and should be high enough to justify the risk and cost of transplantation and protect patient safety. This will allow for more patients to be listed for transplant, more grafts to be accepted, more transplants to be performed, and will allow centers to innovate and develop new transplant options while remaining within the accepted standard. If centers fall below this first measure, a second risk adjusted analysis should be performed using very well-defined variables such as recipient/donor age, DCD, etc. Centers that meet the unadjusted pass/fail threshold or the risk adjusted analysis should not be flagged for performance review. No additional metrics should be added unless and until the impact of this change is evaluated.

Regardless of whether or not this recommendation is adopted we strongly believe that Red Zone flagging criteria should be established at levels that ensure that no more than 2.5% of programs—the true outliers—are flagged for each review cycle. This change has the potential to increase U.S. patient transplant opportunities due to reduced risk aversion by transplant programs and to save lives.

Finally, ASTS believes that statistical significance of self-prescribed thresholds are not clinically meaningful. The current OPTN/MPSC practice of deeming about 10% of all organ programs in need of performance review every 6 months is not well founded in the professional quality realm. ASTS thinks the OPTN proposal, while thoughtful and indeed sophisticated, will not result in substantial positive change in behavior. In addition, applying multiple metrics at the same time could negatively impact the transplant eco-system. The ASTS continues to be optimistic about

transplantation and believes that we have one of the best and safest transplant systems in the world. We look forward to working with all involved in introducing more collaboration to the field.

Our responses to questions raised in the OPTN proposal are included as an Attachment.

References

1. https://asts.org/docs/default-source/regulatory/asts-white-paper-on-optimization-of-transplant-center-assessment-january-12-2021.pdf?sfvrsn=43a46d3_2
2. Schold, J. , Miller, C. , Henry, M. , Buccini, L. , Flechner, S. , Goldfarb, D. , Poggio, E. , Andreoni, K. & (2017). Evaluation of Flagging Criteria of United States Kidney Transplant Center Performance. Transplantation, 101 (6), 1373-1380. doi: 10.1097/TP.0000000000001373.

Attachment

The OPTN Membership & Professional Standards Committee requests feedback on:

1. *Do you think transplant programs that fall within the performance improvement or "yellow" zone would take advantage of offered assistance and if so, what types of assistance would be most helpful?*

   Interaction within the defined "yellow" zone is voluntary, and reaction to notification of "yellow" zone status will likely vary based on the unique situation, resources, and culture of each program. Access will range from use of educational material and best-practices information to significant interaction with the MPSC such as peer-peer engagement or other interactions.

   The MPSC should be prepared for the possibility that interaction with programs in the "yellow" zone (YZ) will be very labor intensive. Raising the hazard ratios for the YZ and RZ, thus decreasing the number of anticipated YZ and RZ flags would decrease the likelihood of unmanageable MPSC workloads emerging from this policy change.

2. *Would you support the future addition or replacement of the 1-year post-transplant graft survival with a longer-term period-prevalent survival metric, such as a 5-year period prevalent post-transplant graft survival?*

   The fundamental problem is that the longer-term the outcome measure, the more tenuous the link to the actual performance of the Transplant Center (TC) in the perioperative phase and the less control the TC has over those patients forming the long-term cohort. The assessment of the pros and cons would depend on the weighting given to a long-term metric and the hazard ratios or thresholds utilized to determine flagging for the metric. This would be more a measure of patient socio-economic status than transplant center performance as those with better insurance would have better community care over the five-year term.

3. *One of the desired attributes of a good monitoring system is the monitored entity understands the measures being used. In order to ensure this understanding: What types of resources do you anticipate needing to respond to these new metrics?*

a. *Are you comfortable with the concept of risk adjustment or do you think additional education on risk adjustment is needed?*

The problem with risk adjustment is that it results in a moving target for centers. What was an acceptable survival last year may not be accepted in the next cycle, based on changes to the model which cannot be predicted by programs. A second problem is that some factors that are currently in the model, such as peripheral vascular disease and diabetes have a very wide spectrum of disease morbidity, and centers that are more familiar with the PSR models are coding for these risks more liberally than others. A third problem with risk adjustment is that not all variables known to impact survival are included in the model and the process for including variables is opaque. Because of these and other factors, we do not believe that risk adjustment is trusted by transplant centers.

The theory of risk adjustment makes obvious sense, but in reality, the granularity of the patient data necessary to achieve meaningful and fair risk adjustment is simply impossible to obtain.

b. *What education resources do you need to describe these metrics to your patients?*

We do not believe that the new metrics should be adopted, nor do we believe that metrics that require significant patient education are likely to be useful. Any metrics that are adopted should be sufficiently meaningful to patients and sufficiently straightforward to require little or no explanation from health care professionals.