ASTS Request for Counterpoint to AOPO Statement on High Kidney Discard Rate in Transplant Centers

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Endorsed by the ASTS Executive Committee
July 2023

The American Society of Transplant Surgeons (ASTS) is a medical specialty society representing over 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.

The ASTS appreciates the comments of The Association of Organ Procurement Organizations (AOPO) concerning the complexities of our national solid organ deceased donation transplantation processes and our universal desire to provide outstanding care to our transplant recipients while optimizing each incredible gift from our donors and their families. Through the extraordinary generosity and courage of our donors and donor families, the Organ Procurement Transplant Network (OPTN), the Organ Procurement Organizations (OPOs) and the transplant centers, more patients with end stage organ failure have been helped annually with the gift of life through transplantation. As noted in the February 25th, 2022 NASEM report, "the organ donation and transplantation system in the United States is the largest and most sophisticated system of its kind in the world." The COVID-19 pandemic demonstrated the resilience of our transplant system to adjust to significant systemic changes in the health care delivery system. Within a few months the transplant community resumed pre-pandemic volume of transplants under challenging conditions. Remarkably, in a five year time span that included the pandemic, the number of transplants from higher risk donors, such as after circulatory determination of death donors, more than doubled increasing from 3,246 in 2016 to 7,303 in 2021. Thus the transplant community can take pride in accomplishments to date.

In response to Mr. Barry Massa's Op Ed, the ASTS believes it is not fair to donors or their families to say an unused donated organ went to waste. The transplant community can often not know the likely potential function of an organ until it is removed so the anatomy and vascular disease can be determined as well as biopsy results and flow mechanics on pulsatile preservation. Determining the likely function of a donated organ, especially a kidney from donors who are becoming older and with co-morbidities such as years of hypertension and diabetes, is not a straightforward task and transplanting these organs can cause direct harm to patients who receive them.

We agree with Mr. Massa and AOPO that the OPOs and transplant centers are not fully aligned in their outcome measurements as OPOs are driven by the number of organs recovered regardless of their eventual function, and transplant centers are judged by their actual patient outcomes.

It is very difficult if not impossible to assume as stated in the Op Ed that 62% of unused donated kidneys would have been 'viable' for a good clinical outcome if transplanted. An acceptable organ for transplant to an individual patient is a complex decision which takes many factors into consideration. Some patients cannot safely tolerate a donated kidney that may not function very soon after transplant. Other donated kidneys have anatomical complexities that are not appropriate for many patients due to the patient's vascular disease, and may be too risky for any patient to receive. In the remainder of this response, the ASTS provides comprehensive

context in which to view the Op Ed and also directs readers to published analyses, standards, guidelines and recommendations by the ASTS on the topic of organ procurement and organ nonuse.

INNOVATIONS TO ENHANCE TRANSPLANT OPPORTUNITY

The shortage of organs for transplant has long motivated transplant professionals to explore surgical innovations, pursue multiple avenues of research and develop a variety of clinical strategies to enhance access to transplantation. For kidney transplant, efforts to increase living donor kidney transplant through education, reduction of disincentives, expansion of paired kidney donation and altruistic non-directed donation are examples of ongoing strategies. Technological advances with machine perfusion offer unprecedented opportunities to extend the acceptable length of time for organ preservation. Furthermore, these technologies have the potential to facilitate more reliable assessment of organ function especially for the increasing proportion of organs that are at risk for poor or nonfunction. Historical trends clearly demonstrate that the transplant community is constantly striving to increase the opportunity of transplant for patients with end stage organ failure.

ASTS EDUCATION & TRAINING STANDARDS AND SURGICAL PROCEDURAL GUIDELINES FOR ORGAN RECOVERY

ASTS is actively engaged in many efforts to increase access to transplantation for patients with end stage organ failure. For example, in order to optimize the quality of organs procured for transplant, the ASTS has published education and training standards and surgical procedure guidelines for deceased donor organ recovery. Adherence to these guidelines were developed with the goal of standardizing the intraoperative assessment of organs (including abnormal anatomy), surgical procedure, packaging and delivery and expectations of information sharing with the recipient transplant surgeon both before and after the procedure (including need for vascular repair or anatomic reconstruction).

- "Surgical Standards for Surgeons Performing Deceased Donor Organ Procurements for Transplantation." https://asts.org/advocacy/surgical-standards-for-surgeons-performing-deceased-donor-organ-procurements.
- ASTS Procedural Standards for Deceased Donor Organ Recovery. https://asts.org/docs/default-source/public-comments/procedural-standards-for-deceased-donor-organ-recovery---approved-jan.-2022.pdf

COMPLEXITY OF DONOR AND RECIPIENT RISK AND BENEFIT ASSESSMENT

We believe that all stakeholders in the transplant community are dedicated to best practices for organ donation, procurement and transplantation recipient outcomes. Each time a transplant occurs there is great opportunity for benefiting quality and quantity of life but there are also intrinsic peri-operative surgical risks and risks associated with primary nonfunction or poor organ function that impact short-term and long-term patient morbidity and mortality. For each transplant that occurs, complex decision making must occur to assess the risks associated with each particular organ and deceased donor condition and each recipient's condition and readiness for transplant at the time of organ availability. Information from the organ procurement organization (OPO) is transmitted at many time points following the initial organ offer about multiple factors impacting the recipient transplant outcome including the initial intraoperative organ assessment by the procurement surgeon,

post procurement anatomy, potential biopsy results, potential machine perfusion characteristics and logistics associated with organ retrieval and transportation that impact donor organ quality and function.

Layered onto these complex medical decisions are continual perturbations to the process initiated by new federal policies and changes in procedures. Each policy change such as wider geographical sharing of deceased donor kidneys has added new challenges for the transplant community resulting in longer cold ischemia times increasing the risk that organs will not function immediately (delayed graft function), will have reduced function or perhaps not function at all (primary nonfunction). Unintended consequences of this new allocation policy include increased strain on the transplant workforce capacity, increased organ procurement costs, and increased time associated with organ placement. With the numerous changes in allocation policy over the last decade, it is often not possible to understand the impact of each individual intervention on system level outcomes such as organ acceptance and utilization.

Transplant centers constantly strive to adjust to these changing conditions to serve their patients. Transplant surgeons have the challenge of transplanting more complex patients. For example, recipient co-morbidities and operative risks for end stage renal disease (ESRD) patients have increased and is reflected in part by the significant increase over the past decade in candidate age, body mass index (BMI) and diabetes (as the cause of ESRD) at the time of listing for kidney transplant. Furthermore, some aspects of recipient risks at the time of initial transplant evaluation may increase while candidates are on the waiting list thus increasing the chance of an adverse surgical outcome or reduced longevity of graft and/or patient survival.
At the same time that transplant candidate medical complexity has increased, the proportion of "medically complex donors" has also increased. Patients' willingness to accept higher risk donors is another variable that must be considered. Transplant surgeons now have the challenge of transplanting more complex patients with more complex donor organs in a transplant system that initiates regulatory actions that threaten transplant center viability when outcomes are flagged for lower "observed to expected" outcomes. The national outcomes with kidney transplant for example are so high that in many cases, the flagged outcomes are within 1-2% percentage points of the threshold and usually above 90% one year graft and patient survival which is far superior to outcomes for ESRD patients remaining on dialysis.

DONOR ORGAN NONUSE

The nonuse of potential donor organs that has been highlighted as an area for system improvement certainly requires evaluation and strategies to mitigate any modifiable impediments. The ASTS has previously commented in response to the Center for Medicare and Medicaid Services (CMS) Request for Information (RFI) on Health and Safety Requirements for Transplant Programs, OPOS and ESRD facilities. https://asts.org/docs/default-source/regulatory/asts-response-to-hrsa-oamp-rfi-on-the-optn-may-9-2022.pdf
Excerpted from the ASTS response to this RFI is the following:

> *"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 nonuse can be eliminated. … Despite this progress, there are several significant limitations on the degree to which organ nonuse 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 nonuse rates; the greater number of transplants is the relevant metric, not the number not used. 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 nonuse is a predictable and an unsurprising consequence of the different roles played by OPOs and transplant programs."

"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."

We stress that the approach to optimizing donor organ acceptance and use must take into account the entire transplant ecosystem. Pre-operative determination of deceased donor suitability, donor management, organ assessment and procurement surgery, post procurement placement factors including efficient and reliable transportation, recipient medical condition and readiness for transplant and transplant center resources impact organ acceptance and use. The assumption that there is a formula or percentage of procured organs that can serve as a national performance metric has yet to be validated under one set of conditions let alone conditions that are unique to individual communities and are evolving in response to new policies and procedures. To increase utilization of organs from "medically complex donors", the ASTS RFI response recommended changes in organ allocation policies and CMS regulatory metrics, dissemination of best practices, modification of the inpatient prospective payment system that adjust DRG payments to account for the additional costs involved with these transplants and dedication of research resources including transplant-specific NIH funding to investigate strategies to improve functional assessment, reverse acute injury and improve outcomes of these difficult to place organs.

Assignment of arbitrary OPO and transplant center performance metrics that are associated with potential decertification or financial penalties have the potential to silo stakeholders and stifle cooperation. ***Successful minimization of organ nonuse will require a comprehensive approach that incentivizes collaboration, cooperation, trust, research and mutual learning.***

OPPORTUNITY TO ENHANCE COLLABORATION, COOPERATION AND COHESION

The ASTS leadership looks forward to working closely with administrators within the US Department of Health and Human Services Health Resources and Services Administration (HRSA) on strategies to achieve the goals of the Organ Procurement and Transplantation Network (OPTN) Modernization Initiative.

https://www.hrsa.gov/about/news/press-releases/organ-procurement-transplantation-network-modernization-initiative

A successful approach will take into account the complexity of the transplant system, value its stakeholders and consider the potential impact of OPTN and CMS policies and metrics upon the system as a whole..

Changes in complex systems such as organ allocation and utilization require significant time to establish baseline outcomes. Additional changes must be implemented only after this baseline is defined and understood or the new interventions may actually harm system performance.

The ASTS has continually emphasized that the true intent of our national transplant system should be to increase the donation and transplantation opportunities for all patients and their families. The federal government and private insurers have steadfastly refused to create a reasonable bar of outcome metrics and have instead focused on attempting to drive transplant center behavior by redefining metrics and comparing transplant centers to each other – therefore, almost always, some centers must lose even if the benefit of transplant at the relatively 'poorest performing' transplant center is a major advantage in survival and quality of life for their recipient patients. More effort and resources should be focused on optimizing communication and cooperation between donor hospitals and OPOs, and between OPOs and transplant centers to allow this highly complex series of events to become more efficient and lead to more transplant opportunities.

In addition, the universal availability of hypothermic and normothermic technologies needs to be supported by government finances and additional research to further develop these technologies should be supported by federal funding so our citizens receive the best possible organs from our increasingly complex donor population. Currently, pump technology is of varying availability center to center and OPO to OPO. New reimbursement methods or government financial resources must be available to allow transplant centers to be adequately staffed by all levels of transplant team members so that transplants can be performed under optimal conditions for success every day of the year.

We wish to continue to work for the patients' and donors' best interests by increasing transplant opportunities for the citizens of our country. Our US transplant effort has been remarkable considering its origins from a few highly motivated transplant surgeons working within their own hospitals to help create OPOs and then multi-disciplinary teams. Our system needs to now focus on realignment of goals, priorities and removal of disincentives that will permit the transplant centers, OPOs and other stakeholders to work together more seamlessly despite the increasing complexities of transplantation.