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ASTS Analysis of *Out of Sequence Allocation of Donor Organs for Transplant*

The recent *New York Times* article ("*Organ Transplant System 'in Chaos' as Waiting Lists Are Ignored*") highlights the urgent need to address the rapid rise in allocation out of sequence of deceased donor organs (AOOS) to ensure fairness and transparency to waitlisted patients and maintain public trust in the transplant system as a whole while optimizing the benefit of a scarce resource. Multiple ethical principles are relevant to allocation of deceased donor organs for the purpose of transplantation and the ASTS Ethics Committee has provided an ethical framework in which to evaluate AOOS.

It is critical to analyze the systemic pressures driving the extraordinary increase in this unprecedented practice. The recent explosion in AOOS is, an excellent example of the unanticipated consequences of uncoordinated and conflicting regulatory policies, including stricter OPO performance standards, changes in allocation processes intended to share organs more broadly, and transplant program performance standards that disincentivize programs from accepting medically complex organs at risk of non-use. The solution to AOOS as well as other issues in transplantation requires a collaborative public private partnership infrastructure that facilitates cooperation and collaboration.

New OPO Certification Standards

In order to improve the performance of OPOs, in 2020 the Centers for Medicare and Medicaid Services (CMS) finalized new Medicare conditions of participation that require all OPOs to meet the performance level of the top 25% with respect to two metrics: The number of organs procured, and the number of organs transplanted. The result has been extraordinary growth in the number of organs procured that are not suitable for transplantation and the number of organs transplanted out of sequence. At the same time, these new metrics have at least partially achieved their objectives, increasing the number of organs available for transplantation and contributing to record-breaking transplants performed over the past several years.

Broader Organ Sharing Across Regions

Several years ago, in part as a result of litigation and a regulatory mandate from Health Resources and Services Administration (HRSA) (which oversees the transplant system), the methodology used to allocate organs was modified to facilitate broader geographic distribution of deceased donor organs. Under the prior allocation system, the leading cause of disparity in access to kidney (and other) transplantation was the geographic location of the waitlisted patient. At the time, the allocation system was reliant on the arbitrarily drawn boundaries of the 58 OPO Designated Service Areas (DSAs) and 11 OPTN regions. Neither DSAs nor regions were constructed with a consistent size or population, and neither was intended to be used for organ distribution. A 2023 OPTN Monitoring Report indicates that the change in the allocation methodology was at least moderately successful: Transplant rates increased after the removal of DSA and regions as an allocation primary factor, and equity in access to transplants increased for several key populations, including blacks, Asians, candidates with over three years on the waiting list, pediatric candidates and highly

sensitized patients. But the same allocation changes also disrupted longstanding relationships between OPOs and their local transplant centers and increased the complexity of organ placement. While many of the consequences were anticipated in broad terms, the magnitude and ripple effects of the allocation changes--including their contribution to escalating AOOS—were not.

<u>Disincentives to Accept Organs at Risk of Non-Use</u>

The complexity of the issue is exacerbated by conflicting regulatory incentives: While OPOs are encouraged to recover as many potentially transplantable organs as possible, transplant programs are strongly incentivized to maximize one-year graft survival and therefore to decline organs that may fail. The Scientific Registry of Transplant Recipients (a HRSA contractor) publishes "program specific reports" that compare the risk adjusted one year graft survival of transplant programs against one another. Falling from a "three star" to a "two star" rating not only results in reputational loss but also has the potential to trigger in a transplant program's exclusion from private payer networks, which may in turn place a transplant program in financial jeopardy and ultimately impair patient local access to transplantation if the program is down-sized or closed. *Because transplant outcomes have improved so dramatically, a transplant program runs this risk even if its risk-adjusted one year graft survival drops from 95% to 94%*. Not surprisingly, the star rating system has resulted in some transplant programs' reluctance to accept organs that are medically complex and at risk for nonfunction. HRSA has retained this rating system despite the well-recognized organ acceptance disincentives the system has created. These disincentives have also contributed to AOOS by incentivizing OPOs to offer organs at risk of non-use to select transplant programs that have the resources and expertise to accept them.

All this is not to excuse the exponential recent escalation in AOOS—escalation that has been well known to the OPTN, to HRSA and (presumably) to CMS for the past two years. The only action taken was the OPTN's adoption of a policy entitled "Open Variance for Expedited Placement" that created a pilot program pathway under which AOOS criteria was required to be defined and monitored—a program whose implementation was blocked by HRSA. On February 21, 2025, HRSA issued a directive to the OPTN which (belatedly) announced HRSA's conclusion that the governing regulations do not authorize out-of- sequence offers by OPOs at all, but (somewhat inconsistently) authorized the OPTN to implement expedited placement protocols in accordance with the previously blocked policy. We are hopeful that implementation of the HRSA directive will restore the integrity of the waitlisting process.

Unfortunately, because of the systemic pressures at work, we believe that it is likely to take more than a government directive to address this and many other major challenges facing the transplant ecosystem. While the directive will undoubtedly reduce AOOS, it appears likely that, if OPOs are no longer authorized to allocate organs out of sequence except pursuant to a protocol approved by the OPTN, the number of organs that are procured but not transplanted will increase. The number of organs procured but not transplanted is of great concern to patients, providers, and policymakers alike—but organ nonuse will remain at unacceptably high levels unless and until the

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counterproductive and internally inconsistent incentives created by the various government agencies involved in regulating transplantation are addressed.

Neither AOOS nor organ nonuse—nor any other of the major challenges facing the transplant system—can be solved without the voices of the transplant community—recipients, donors, family members, transplant programs, OPOs, histocompatibility labs, professional associations, and others—at the table. The U.S. transplant system is the most successful in the world, saving thousands of lives annually. The ability of transplant programs to continuously innovate and improve practices has been a key factor in this success. However, the transplant system is an ecosystem in delicate equilibrium that necessarily involves nuanced trade-offs to balance equity, access, transparency and utility. Well-intentioned policy changes often result in unanticipated consequences with significant repercussions for patients.

It is with this lesson in mind that we express serious concerns about HRSA's margination of transplant community voices as part of OPTN modernization. The OPTN, which historically has represented the collective voices of transplant recipients, donors, family members, transplant programs, OPOs, histocompatibility labs and other transplant stakeholders—has been eliminated as an organization, leaving only a Board whose members will be vetted and approved by HRSA. Under the new model, the transplant system will be operated by HRSA through as many as fourteen contractors, none of which has transplant expertise, without expert clinical input or oversight by the transplant community. At the time of writing, HRSA's Division of Transplantation includes three transplant professionals, and the Chief of the Division was recently let go as part of the dismissal of probationary employees.

Sometimes, unanticipated consequences can be anticipated.