ASTS
American Society of Transplant Surgeons

Accelerated placement of hard-to-place kidneys: Protocol 1: Pre cross clamp placement of KDPI 75-100 kidneys

While ASTS strongly supports efforts to reduce the number of organs that are procured but not transplanted, we regretfully cannot support the proposal as written. We strongly believe that the proposal has the potential to substantially disadvantage waitlisted patients and undermine the fragile public trust in the organ allocation system that the OPTN and the transplant community have iteratively established over decades through a comprehensive, evidence-based, and publicly vetted process. Below, we offer the rationale for our concerns and suggested guidance for revision of the proposed Protocol that would allow us to support it in full.

We have two major concerns with the proposed Protocol: (1) the KDPI threshold of 75% is too low; (2) the proposed evaluation metrics include no assessment of the impact on wait-listed candidates bypassed in the process of engaging in out of sequence allocation of a very large number of kidneys. Furthermore, the implementation of these variance protocols at the same time that the transplant system is being perturbed by an enormous and evolving reorganization (OPTN Modernization Initiative) and a new Increasing Organ Transplant Access (IOTA) Model will confound the analysis and obscure the conclusions about the protocol outcomes.

The proposed 75% KDPI cutoff will presumably include well over 25% of the kidneys from the DSAs of the five proposed participating OPOs offered to adult kidney candidates, as many of the KDPI < 75% kidneys will be placed with pediatric recipients, to recipients receiving other lifesaving organs in addition to a kidney, and to broadly sensitized candidates. The 75% cutoff does not correspond with high-KDPI candidate consent, which occurs at an 85% cutoff, or with center practices, which typically do not view kidneys with KDPIs less than 85 as “high-KDPI” kidneys at all. The Protocol as proposed would simply serve as a bypass conduit for massive numbers and overall share of procured kidneys to be placed outside of the standard allocation framework. If the intent is, as stated in policy and the title of the proposal, to accelerate the placement of “hard-to-place” kidneys, then the KDPI threshold or cutoff utilized must be much higher than 75%. If another intent of the Protocol is indeed, as stated in policy, to gain information about best practices and outcomes for decreasing non-utilization, then any post-implementation measurements or metrics will be more valuable if the cohort studied is limited to truly high-KDPI kidneys and thus enriched with those organs that are in fact at markedly elevated risk of non-use. Setting the KDPI threshold at 75% belies the stated goals of the policy as envisioned by the OPTN Expeditious Task Force, dilutes the potential value of the observations to be made from the Protocol, and maximizes the risk of inequity to the thousands of wait-listed candidates who will be deprived organ offers through reliance on an expedited pathway for kidneys that would otherwise be transplanted in-sequence through a vetted and transparent allocation process. A **KDPI threshold of 90%** for this Protocol would mitigate a lot of the equity concerns with the proposal while focusing it precisely on the stated goals of the OPTN Expeditious Task Force.

The lack of sufficient rigor in the scientific approach (insufficient details and requirements for variance proposal application and reporting) for evaluation of variance protocols and the lack of substantive, quantitative, and holistic post-implementation monitoring plans for variance protocols continues to be a weak point in the proposed utilization of so-called accelerated placement Protocols. One of the stated goals of the policy allowing development of variance Protocols for allocation was the accrual of information that could inform the transplant community and provide insights and tools for modifying national policy in ways that will decrease rates of organ non-utilization and increase transplant volumes. The proposed Protocol does not mandate a coherent, holistic post-implementation monitoring program, and does not evaluate equity for candidates bypassed by the Protocol. We therefore believe it likely that this approach will not yield data that is sufficiently reliable or generalizable to inform efforts to formulate national variance criteria moving forward.

We support efforts to decrease the number of organs procured but ultimately not transplanted and efforts to increase the number of transplants performed. We recognize that the current allocation system is imperfect, and we are cognizant of the dynamic tension between utility and justice. The OPTN has done a reasonably good job of balancing those competing interests over the years, particularly considering the often apparently irreconcilable differences in opinion of some of the key transplant ecosystem stakeholders. One of the key strengths of the OPTN is its deliberate policy development cycle, with robust public comment and reliance on data-driven decision making. We believe that a Protocol with an inappropriately wide inclusion scope, as embodied in the current proposal, circumvents the advantages of the OPTN's historic, highly deliberative organ allocation policy-making process and potentially does a disservice to the patients whose lives depend on the equity of the system.

For these reasons, we oppose adoption of the proposed Protocol in its current form. We offer the following suggestions to address these concerns:

- Conduct a root cause analysis of the reasons for organ non-utilization, focused primarily on the area of most pressing concern—the non-utilization of deceased donor kidneys. To date, there has been no root cause analysis of the non-utilization of the thousands of unused organs in the US. Performing such an analysis has been discussed at Board meetings and endorsed by OPTN leadership, yet no action appears to have been taken. Absent this difficult but critical investigation, we believe that it will be extremely difficult, if not impossible for the Executive Committee or any other entity to engage in well-informed policy development on allocation through the proposed variance process or otherwise.
- Establish a uniform definition of deceased donor kidneys at risk of non-utilization to be used in future variance protocols eligible for approval.
    - ASTS believes that consideration should be given to the following criteria:
        - Kidneys that reach 6-hours CIT not on pump or 8-hours on pump without acceptance for standard adult candidates.

- KDPI ≥90%.
- Any kidney with **DCD** donor status and donor **age greater than 60 years**.
- Biopsy: Severe arterial disease, interstitial fibrosis, or GS>10% on biopsy.
- Procurement gross anatomic criteria: Hard renal arterial plaque.

- **Change the KDPI cutoff for this proposed Protocol to greater than or equal to 90%.** This change would be critical in optimizing the potential value of the Protocol while assuaging community concerns about impairment of equity.
- Establish standard criteria for reporting pre- and post-variance data in future Protocols.
    - Those data elements might include, for example, reasons for expedited placement; outcome of expedited placement process (Accepted, Transplanted, Not utilized and reasons for non-utilization); CIT (at the time of expedited placement, at the time of allocation; and at the time of transplant); impact on the recipient (short term (Initial DGF or not) and long term (time to dialysis free, one year outcomes)); number of waitlisted patients bypassed by the variance and modeling of the estimated impact on bypassed candidates); pre/post efficiency; pre/post organ utilization.

We appreciate the opportunity to comment on this proposed Protocol and look forward to working with the OPTN to ensure that all organs appropriate for transplantation are utilized, while balancing stewardship of a scare resource with equity for all patients on the waiting list and maintaining the public's hard-won trust in the OPTN and in the organ allocation system.

ASTS Position: Oppose