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RE: Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

Dear Dr. Rudow, Dr. Kim, and Dr. Olaitan:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) request for feedback on “Efficiency and Utilization in Kidney and Pancreas Continuous Distribution.”

Maximizing patients’ access to kidney transplant—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. The society stands ready to work with OPTN, and the OPTN Kidney and Pancreas Committees, to achieve this goal. The OPTN Kidney and Pancreas Committees have put several years of work into envisioning a future system of continuous distribution, and as the operational considerations and next steps outlined in the request for feedback make clear, more crucial work remains before this vision can be finalized and implemented.

Accordingly, ASN supports the Wednesday, September 13, 2023, announcement that the originally anticipated timeline for progression to continuous distribution for kidney and pancreas is being revised to allow the committees to further consider and apply approaches to increase organ usage and increase efficiency in their eventual proposals. ASN appreciates OPTN’s

commitment to creating numerous opportunities for the entire community to provide input to the task force's important work, including through the forthcoming September town hall, and stands ready to support this effort however possible.

Identifying strategies to mitigate the growing number of organs that go unused, tackling the root causes of out-of-sequence offers and "list-diving," expanding adoption of best practices to increase efficiency, and embracing emerging science in terms of organ donation, recovery, and preservation, are all examples of efforts that will strengthen the transplant ecosystem overall and contribute to a more successful eventual new approach to kidney and pancreas allocation. Increasing transparency, particularly to patients, is likely to play a key role in achieving many of these objectives. In addition to policy considerations, ASN also highlights that numerous advancements in infrastructure and technology must first be achieved to realize the promise of continuous distribution.

This task force, together with the OPTN Modernization Initiative, represent important opportunities to implement structural and policy changes, and invest in innovative technologies, that will pave the way for optimal eventual adoption of a system of continuous distribution. Throughout these efforts, ASN urges OPTN, the task force, the Health Resources and Services Administration, and other stakeholders to continue to prioritize maximizing patient access to transplantation and ensuring that access as equitable regardless of race/ethnicity, socioeconomic status, geography, and sex/gender.

While ASN strongly supports the integration of the results of the task force into the continuous distribution system, the society also recommends that OPTN consider opportunities to adopt policy changes such as those described above on an ad hoc basis in advance of implementation of the continuous distribution system.

ASN offers input on select aspects of the request for feedback on "Efficiency and Utilization in Kidney and Pancreas Continuous Distribution." Again, the society commends the committees for their extensive consideration of these wide-ranging operational details.

Continuous monitoring

As this multifaceted, detailed paper makes clear, there are a host of nuanced technical aspects that must be considered in the transition to a system of continuous distribution. ASN commends the committees' and OPTNs' efforts to identify the best possible approaches to addressing these complexities, including seeking community input, in advance of policy finalization. As we move, in the coming years, into implementation, close monitoring of the new system utilizing both process measures and outcome measures will be essential to allow us to assess whether the system is meeting its intended goals and if there are unintended adverse consequences. The results of these monitoring efforts should be shared with the research community in as close to real-time as possible to facilitate understanding of the effects of the new system and to support opportunities for improvement to increase patient access and equity as new knowledge is obtained.

Released Organs

Overall, ASN encourages prioritizing minimizing the risk of potential organ nonuse, improving utilization and thereby increasing access to transplantation, in any policy governing how released organs are handled.

The committees seek input regarding whether to "carry over" certain refusals from an original single match run to subsequent released kidney match runs (which may occur in instances such

as when a program has accepted an organ and subsequently choose not to transplant the organ, releasing it back to the organ procurement organization). Given that a released kidney would be in jeopardy of discard, ASN believes that utilizing a shortened list of potential centers who are willing to accept the organ makes sense. OPOs should run a released organ match run carrying over refusal reasons from the original match run.

ASN recommends that all refusal codes be carried over, not just the list of suggested refusal codes included in Appendix A. Carrying over some refusal codes and not others is likely to result in gaming: some centers may disproportionately select the decline codes that do not carry over. In particular, ASN recommends that the projected cold ischemic time (CIT) be carried over, as the time will likely have already accrued. However, this approach would need to be monitored and studied to understand the effect on utilization over time.

As noted later, ASN does not support “carrying over” qualifying refusals from the single kidney match run to the dual kidney match run. The society believes centers would likely have very different reactions to being able to use both kidneys versus one kidney, and would be most inclined to consider them for patients who have been prespecified as dual kidney candidates.

ASN generally agrees with the committee’s recommendation to support an increased weight for placement efficiency on the released kidney match run. However, safeguards should be put in place to ensure increased efficiency weights do not allow a center to game the system by accepting a kidney and subsequently decline it, releasing it back to the pool in a manner that ensures that it returns to the same center. It is impossible to address the extent to which placement efficiency should be prioritized on the released kidney match run without modeling.

Crucially, rates of organ releases by centers should be tracked and publicly reported.

National Kidney Offers and Kidney Minimum Acceptance Criteria Screening Tool

The differences between Kidney Minimum Acceptance Criteria (KiMAC) and organ offer filters are subtle and confusing even to experts who have given significant attention to these issues. ASN recommends that the nomenclature be modified so that there is one set of program level filters and one set of patient level filters to limit confusion.

The committee recommends that KiMAC would apply to candidates on the last 92% of the match run, based on the program’s indicated donor criteria. ASN respectfully posits that it should instead apply to 8% of the candidates. Currently, centers are less likely to accept marginal kidneys for patients at the top of the list and more likely to accept them for those patients who have accrued fewer allocation points. As a result, centers tend to be the most selective for patients with the highest priority. It makes more sense to apply filters (or KiMAC) to the top of the list rather than the bottom of the list. Also, centers should be able to determine where to set their threshold (i.e. to which sequence numbers they wish to apply these filters).

ASN believes that it should be up to the discretion of each center which patients KiMAC applies to, as opposed to having a blanket nationwide mandate (such as based on CPRA, or for whom the program’s minimum acceptance criteria does not apply). Further research into clearly defining “hard to place” kidneys to improve the utilization of such organs using KiMAC should continue.

Dual Kidney Allocation

ASN supports allocating kidneys as dual via a separate, dual kidney specific match run, however, the society notes that offering dual kidneys with KDPIs as low as 35% would not make sense. The goal of dual kidney allocation is to provide a patient survival advantage over single high KDPI kidney transplantation, and to encourage utilization of more medically complex kidneys—kidneys that are definitionally not going to have a KDPI in the vicinity of 35%.

ASN does not support “carrying over” qualifying refusals from the single kidney match run to the dual kidney match run. Dual kidneys should have their own match run. The society believes centers would likely have very different reactions to being able to use both kidneys versus one kidney and would be most inclined to consider them for patients who have been prespecified as dual kidney candidates.

Clearly defined criteria should be established for when kidneys should be considered for dual placement. The committees and/or OPTN should identify characteristics that lead to a kidney being considered primarily for dual placement and develop policy so that all OPOs use those same donor factors in their decision-making, as opposed having each OPO make its own determination as to whether kidneys are run as a single or a dual match run. As part of the considerations regarding dual kidney allocation in the new system, ASN also encourages OPTN to surface the successful features KSAM for duals in the past.

The committees inquire whether programs should be required to obtain patient consent prior to opting candidates into receiving dual kidney offers. ASN strongly encourages the use of prospective shared decision-making tools in informing the decisions made on patients behalf regarding organ offers, as well as greater routine retrospective information sharing with patients regarding organ offers that were declined on their behalf. However, there is nothing inherently “bad” about a dual kidney, and studies have shown their function and relative benefit to being off dialysis. Education and consent prior to the surgery are essential, but a nationwide policy mandating prior consent at the time of listing does not seem necessary at this time.

Kidney-Pancreas Offers

The committees inquire what candidate characteristics should be considered in determining the mandatory Kidney-Pancreas shares threshold. ASN supports maintaining the 250 nautical mile distance for facilitated pancreas bypasses as well as the proposed qualifying criteria, including a metric to weigh the severity of hypoglycemic unawareness. For example, a threshold of events per year could be considered (recognizing, however, that one event is enough to change an individual’s mental function and capacity.)

In sum, ASN appreciates OPTN’s and the committee’s dedication to ensuring every aspect of the anticipated transition to continuous distribution, including factors that will be considered by the forthcoming task force, are given appropriately detailed consideration. The society appreciates the opportunity to provide input and looks forward to continuing to do so through every possible avenue moving forward. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,



Michelle A. Josephson, MD, FASN
President