May 30, 2024

Organ Procurement and Transplantation Network (OPTN)
United Network for Organ Sharing (UNOS)
700 North 4th Street
Richmond, VA 23219

RE: Protocol 1: Pre cross clamp placement of KDPI 75-100 Kidneys

AOPO appreciates the opportunity to comment on the recently published *Protocol 1: Pre cross clamp placement of KDPI 75-100 Kidneys* for the accelerated placement of hard-to-place kidneys. AOPO commends the Rescue Pathways Workgroup of the Expeditious Task Force for its work to improve utilization. I am writing on behalf of the Association of Organ Procurement Organizations (AOPO), representing 48 federally designated, non-profit Organ Procurement Organizations (OPOs) in the United States, serving millions of Americans. As an organization, AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaboration with OPOs, other stakeholders, and federal agencies to continue this nation's transplantation success while consistently improving towards the singular goal of saving as many lives as possible.

Transplant Center Collaboration

In 2023, 28% of kidneys recovered by OPOs were not accepted for transplant-by-transplant centers, with cold ischemic time a significant factor in transplant center decisions to decline kidney offers. Expedited placement protocols can facilitate the utilization of hard-to-place kidneys because OPOs are able to identify programs likely to accept kidneys prior to or shortly after recovery, reducing allocation time and, as a result, cold ischemic time. Protocol 1 provides a framework to identify kidneys that are appropriate for expedited placement, with transplant centers likely to accept and transplant these hard-to-place kidneys. Critical to the Protocol's effectiveness in increasing utilization is transplant center accountability for their role and responsibilities in the Protocol. AOPO encourages the Committee to include specific requirements for transplant centers to include at a minimum:

- Precise and enforced timeframes for responses to offers.
- A commitment to timely pre-recovery review of offers ***by decision makers*** to ensure true interest in offers.
- Timely response to offers once all necessary information (biopsy, pump numbers) is available post-recovery.

These components are critical because failure to thoroughly review offers, confirm recipient matching, and respond pre-recovery, as well as post-recovery declines based on information available at the time of offer, increase cold ischemic time and create logistics inefficiencies that impact acceptance and transplantation of these already hard-to-place organs.

AOPO recommends real time monitoring of late and post-recovery declines to identify and address patterns of these declines including removal and replacement of participating transplant centers.

Clarification - Identification of Candidates; Dual Kidneys

The Protocol summary states *"[p]articipating transplant programs will have a pre-identified list of transplant candidates willing to accept kidneys from deceased donors with a KDPI of 75 percent or higher. They may identify two transplant candidates from their program for whom they would accept such an offer."* AOPO encourages the Committee to allow the transplant center to not limit the number of candidates eligible for an offer to two and to allow transplant centers to identify all candidates for whom they would accept the kidney to increase the likelihood of placement. The Task Force should outline how candidates at participating centers will be prioritized with the goal of facilitating efficient allocation among target centers to reduce cold ischemic time.

The Protocol should address treatment of dual kidney offers. Some kidneys from medically complex donors significantly at risk of non-use may be accepted for transplant if offered as dual kidneys. These kidneys are often not used due to accumulated cold ischemic time because current allocation policy does not allow allocation of dual kidneys until further down the match run in densely populated areas. Allowing allocation of dual kidneys for qualifying kidneys would avoid non-utilization in some cases.

Selection Criteria

The Task Force indicated that geographic proximity to the OPO is a factor for selection of transplant centers for participation. AOPO recommends the Task Force reconsider the relevance of proximity. OPOs routinely allocate these hard-to-place kidneys with transplant centers outside their donation service area (DSA) and transplant centers routinely accept kidneys from OPOs located in other areas of the country. Moreover, it is not clear what the measure of proximity would be – donor hospitals in one DSA may be closer to a non-DSA transplant center than transplant centers in the OPO's own DSA. Limiting participation based on proximity to the OPO could unnecessarily and inappropriately exclude transplant centers likely to accept these kidneys. Additionally, this factor could eliminate an OPO with a high volume of >75 KDPI kidneys that has no transplant centers in their DSA willing to accept the kidneys.

AOPO recommends including primarily OPOs with a high volume of >75 KDPI kidneys as including too many low volume OPOs would not likely provide the necessary data and insight to inform protocol development. The Task Force should also consider including a larger pool of transplant centers for participating OPOs with a high volume of >75 KDPI kidneys as transplant centers may exhaust their list of candidates appropriate for these kidneys.

Monitoring and Metrics

In addition to the Task Force's proposed evaluation metrics, AOPO recommends additional metrics. Improving equity in transplant is a top priority for AOPO and its members and was identified as an opportunity for improvement by the National Academies of Science,

Engineering, and Medicine (NASEM) in its report Realizing the Promise of Equity in the Organ Transplantation System. It is imperative that any proposed protocol for expeditious placement include an assessment of its impact on equity in transplant to ensure the protocol supports and does not undermine efforts to improve equity in access to transplant.

Additionally, because cold ischemic time is a primary factor in transplant center declines for these organs, it is important to monitor the impact of the protocol on cold ischemic time and compare with kidneys placed outside the protocol.

Thank you for your consideration.

Sincerely,

Colleen McCarthy
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Vice President of Organ & Tissue Donation
Versiti Wisconsin