

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup**Meeting Summary****May 20, 2022****Conference Call****Rachel Forbes, MD, Chair****Oyedolamu Olaitan, MD, Vice Chair****Martha Pavlakis, MD, Chair****Jim Kim, MD, Vice Chair****Introduction**

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 5/20/2022 to discuss the following agenda items:

1. Operational Considerations: En Bloc Allocation
2. Operational Considerations: National Offers

The following is a summary of the Workgroup's discussions.

1. Operational Considerations: En Bloc Allocation

The Workgroup discussed en bloc allocation policy and appropriate adjustments to operationalize en bloc allocation in a continuous distribution framework.

Presentation summary:

Current en bloc allocation policy was implemented in 2019, and states that the host Organ Procurement Organization (OPO) must offer kidneys from deceased donors less than 18 kilograms (kg) en bloc, if both kidneys are recovered. Centers must opt candidates individually to receive en bloc offers. The Kidney Donor Profile Index (KDPI) is masked in the OPTN Donor Data and Matching System for en bloc donors, but the en bloc match run follows the same sequence as donors with a KDPI 0-20 percent. This sequence of allocation prioritizes pediatric and low estimated post-transplant survival score (EPTS) candidates. En bloc kidneys are allocated according to the KDPI 0-20 percent sequence because graft and patient outcomes are similar to low KDPI kidneys. Since implementation, en blocs have been well utilized by low EPTS candidates.

Allocating en bloc kidneys under continuous distribution will require tweaks to the policy, as continuous distribution moves away from sequences and classifications, and the Kidney-Pancreas Simultaneous Allocation Model (KPSAM) request will model KDPI and EPTS on a continuous scale. A KDPI is needed for these donors in order to give appropriate composite allocation scores (CAS) to each patient in the match run.

- The KDPI currently used in allocation assumes the candidate receives a single kidney transplant, and so does not reflect the actual expected outcomes for receiving the kidneys en bloc
- The KDPI equation is a function of donor weight, and generally speaking, as a donor's weight increases, their KDPI decreases, translating to better expected outcomes
- Because these donors are small, they will have a high KDPI - the cumulative distribution of KDPI for deceased donors weighing less than 18 kg shows that a very small proportion of donors weighing less than 18kg actually fall between 0 and 20 percent KDPI

The original calculation that KDPI is based upon, known as the Kidney Donor Risk Index (KDRI), was published in 2009 and included en bloc as a factor adjusted for in the original KDRI calculation. This factor accounts for expected benefit in post-transplant outcomes for an en bloc transplant. The en bloc factor wasn't initially included in the KDPI calculation because the use of KDPI in allocation policy predates the specification of which donors should be allocated en bloc

Potential solutions to en bloc allocation in a continuous distribution framework:

- Account for the benefit of receiving en bloc transplant in the calculation of KDPI
 - This factor is already in the literature, and the post-implementation monitoring report shows the current policy is working well
- Assign all en bloc donors the same KDPI
 - Would require further conversation and potentially submission of a data request to inform and justify what KDPI would be appropriate to assign en bloc donors

Summary of discussion:

One of the Chairs asked for clarity on the en bloc factor, and staff confirmed that the en bloc factor was in the 2009 published KDRI formula, but isn't currently used in the KDPI calculation. Staff explained that the original KDRI formula includes a number of characteristics that are not used in the KDPI calculation, such as cold ischemic time, as these characteristics can be hard to predict or may not be known at time of match run.

One Chair remarked that it would be artificial to assign all en bloc donors the same KDPI, and recommended moving away from that blunt approach. The Chair continued that the proportion of en bloc donors falling into the 0-20 percent KDPI range seems to mirror the proportion of recipients receiving these en bloc kidneys. The Chair expressed support for incorporating the en bloc factor into the KDPI calculation for en bloc donors, noting that this approach makes the most sense.

Another Chair pointed out that utilizing the en bloc-adjusted KDPI formula would be new to the system, with less consistency across en bloc kidney donors than simply assigning a standard, single KDPI to all en bloc donors. The Chair noted that many programs don't accept en bloc offers due to related risks, such as thromboses. The Chair asked if en blocs are a separate run, and staff confirmed that donor weight of less than 18kg triggers the en bloc-specific match run, which includes only candidates from centers who have opted in to receive en bloc offers. The Chair remarked that it seems appropriate and straightforward to update the KDPI calculation to incorporate the en bloc coefficient for these donors. The Chair added that this is a small group of donors, and that the en bloc coefficient is static.

A member asked if the Workgroup could review retrospective data utilizing the updated en bloc KDPI and reviewing outcomes. Staff explained that this would be an additional effort, and would likely require the Workgroup to submit a formal data request. The member noted that, if the Workgroup decides to come up with a standard KDPI, the KDPI chosen should be data-driven.

A third Chair agreed with the staff recommendation, remarking that en bloc kidney transplants tend to have good outcomes and that it makes sense to include the en bloc coefficient. The Chair asked what would happen if the accepting program decides to split the en bloc kidneys. Staff explained that current policy requires the OPO to run a new match run with the unmasked, non-en bloc adjusted KDPI. Staff noted that, in practice, those organs are sometimes placed with a candidate further down the original match run. Members agreed that the en bloc policy should be operationalized and allocated using an unmasked, en bloc-adjusted KDPI.

One Chair remarked that en bloc transplantation in general is not as straightforward, pointing out that en bloc offers vary. The Chair provided an example, noting that some two year old donors may qualify as

en blocs the same way a two month old donor would, despite clear differences in size and complication. The Chair continued, explaining that the two year old kidneys could be large enough to be split and transplanted individually successfully, but that there are much greater risks of a two month old en bloc to the recipient in terms of surgical complications. Staff asked if this consideration should be accounted for within the allocation system, or if this should factor more in to something surgeons evaluate on a case by case basis. Staff explained that allocation policy typically tries to balance allocation rules and the nuances of offer decision making that can't always be accounted for. The Chair responded that this consideration is surgeon dependent, as some surgeons are much more comfortable working with small en bloc kidneys.

One Chair noted that the candidate opt-in could lead to lost efficiency, with programs opting in for offers they don't take. Staff noted that, in looking at the Two-Year Post-Implementation Dual and En Bloc Kidney Allocation Monitoring Report, fewer centers actually perform the transplants than receive the offers. Staff added that this would likely be a separate issue from building the CAS.

A Chair encouraged the Kidney Committee to consider prioritizing en bloc kidneys for chronically hypotensive dialysis patients. The Chair explained that some patients evaluated for transplant are chronically hypotensive on dialysis, and that these patients in many circumstances are not made candidates. The Chair continued that those chronically hypotensive patients who do become candidates have a very high chance of primary non-function. The Chair remarked the allocation system should preferentially allocate very small kidneys, as from pediatric donors with normal blood pressures around 60 or 70 over 40, to these chronically hypotensive candidates who would otherwise not be considered a candidate for transplant. The Chair noted that this could be hugely beneficial to those patients, and improve access to a subgroup of patients that otherwise do not benefit from transplant.

The Workgroup achieved consensus to utilize an en bloc-adjusted KDPI for en bloc kidney allocation.

2. Operational Considerations: National Offers

The Workgroup discussed national kidney offers and the policy requirement to turn allocation of national kidney offers to the Organ Center.

Presentation summary:

OPTN Policy requires OPOs to contact the OPTN Contractor for assistance allocating kidneys to certain "national" candidates – or candidates outside of the 250 nautical mile circle. Typically, kidneys that are allocated "nationally" are considered hard to place kidneys, as most nearby programs have declined the organ.

There is variety in feedback from OPOs regarding this requirement with some OPOs wanting to offer organs nationally themselves. These OPOs are generally larger, with a robust staff and the systems and transportation logistics in place to coordinate national placement. Other OPOs, however, rely on the OPTN Contractor's assistance to place these organs.

Recommendation: allow OPOs to request assistance from the OPTN Contractor to place any organs, but do not require OPOs utilize the OPTN Contractor. This would be the same across all organ types.

Summary of discussion:

One of the Chairs asked the Workgroup if any members had experience that would suggest the recommendation isn't the best pathway. The Chair continued that the recommendation seems reasonable, to allow the OPTN Contractor to be a resource to OPOs across the country, but not a mandatory requirement. Another Chair agreed that this is reasonable.

The Workgroup achieved consensus to allow, but not require, OPOs to request assistance from the OPTN Contractor to place any organ.

Upcoming Meetings

- June 15, 2022 (Teleconference)

Attendance

- **Workgroup Members**
 - Rachel Forbes
 - Martha Pavlakis
 - Oyedolamu Olaitan
 - Jim Kim
 - Silke Niederhaus
 - Abigail Martin
 - Bea Concepcion
 - Cathi Murphey
 - PJ Geraghty
 - Peter Lalli
 - Rachel Engen
 - Todd Pesavento
- **HRSA Representatives**
 - Arjun Naik
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Representatives**
 - Ajay Israni
 - Bryn Thompson
 - Grace Lyden
 - Jon Miller
 - Nick Wood
 - Tim Weaver
 - Warren McKinney
- **UNOS Staff**
 - Joann White
 - Lindsay Larkin
 - Rebecca Brookman
 - Alison Wilhelm
 - Amanda Robinson
 - Ben Wolford
 - Caitlin Shearer
 - Carol Covington
 - James Alcorn
 - Joel Newman
 - Kaitlin Swanner
 - Kim Uccellini
 - Lauren Mauk
 - Lauren Motley
 - Rebecca Marino
 - Ross Walton
 - Stryker-Ann Vosteen