Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 9/17/2021 to discuss the following agenda items:

1. Welcome & Review of Project Goals
2. Overview Prior Living Donor (PLD) Priority in Current OPTN Policy
3. OPTN Living Donor Committee (LDC) Recommendations on Prior Living Donor Priority
4. Prior Living Donor Priority Discussion and Recommendation of Rating Scale

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

1. Welcome & Review of Project Goals

The Workgroup reviewed the goals of the Continuous Distribution project, including the second phase focus on converting identified attributes into points via rating scales and weights.

Summary of discussion:

The Workgroup had no comments or questions.

2. Overview of Prior Living Donor Priority in Current OPTN Policy

The Workgroup reviewed prior living donor priority in current OPTN policy and kidney allocation, including a history and rationale of prior living donor policy.

Presentation summary:

Prior Living Donor Priority was established in Kidney allocation policy in 1996, with the original intent to “increase awareness of the need for organ donation” and based on the “principle of recognizing commitment to organ donation through the kidney allocation system”.

The OPTN Kidney Transplantation Committee reconfirmed prior living donor priority in 2006 and 2011, determining prior living donor priority is important from both patient care and public perception standpoints. In 2010, prior living donor priority was added to the Kidney Paired Donation (KPD) Pilot Project. Prior living donor prioritization was increased in 2020, in the Kidney Committee proposal to remove donor service area (DSA) and region from kidney allocation.

Current kidney policy 8.5.E Prior Living Organ Donors states that a kidney candidate will be classified as a prior living donor if all of the following conditions are met:
1. The candidate donated for transplantation, within the United States or its territories, at least one of the following
   - Kidney
   - Liver segment
   - Lung segment
   - Partial pancreas
   - Small bowel segment

2. The candidate’s physician reports all of the following information to the OPTN
   - The name of the recipient or intended recipient of the donated organ or organ segment
   - The recipient’s or intended recipient’s transplant hospital
   - The date the donated organ was procured

Heart, Intestine, Liver, Lung, Pancreas, and Vascular Composite Allograft (VCA) do not currently have prior living donor priority policies. The Lung Committee’s continuous distribution proposal includes priority points for all prior living donors.

Summary of discussion:

One of the Chairs expressed surprise that liver allocation did not include prior living donor priority, and asked if every organ will discuss and consider prior living donor priority in continuous distribution frameworks. Staff confirmed that each organ will discuss prior living donor prioritization, and shared that a cross-organ workgroup made up of organ-specific committee leadership had previously determined that prior living donor priority should be consistent across organs.

One member recommended that KPD also consider increasing prioritization for prior living donors.

One Chair asked if prior living donors received priority for a kidney, regardless of the organ type donated. Staff confirmed that any prior living donor who donated a kidney, liver segment, lung segment, partial pancreas, and/or small bowel segment would qualify for prior living donor priority in kidney allocation. A member asked if the Lung Committee decided to organize prior living donor priority similarly in lung continuous distribution allocation, and staff confirmed that a prior living donor of any organ would qualify for prior living donor priority in the lung continuous distribution allocation framework currently out for public comment.

A member asked if VCA living donors would qualify for prior living donor priority in kidney allocation, and whether prior living donors receive priority in VCA allocation. Staff clarified that VCA donors are not currently eligible for prior living donor priority in kidney allocation, and that VCA allocation does not currently have prior living donor priority.

3. OPTN Living Donor Committee Recommendations on Prior Living Donor Priority

The Chair of the OPTN Living Donor Committee presented the Living Donor Committee’s prior living donor priority recommendations for kidney and pancreas continuous distribution.

Presentation summary:

After a need for a consistent global approach to prior living donor priority in continuous distribution was identified, the Living Donor Committee was asked to develop recommendations for a cross-organ approach to prior living donor priority in the continuous distribution context. The Living Donor Committee held extensive, deliberate discussions to develop the recommendations while considering medical and ethical justifications. The following recommendations are provided to the organ committees to use as guiding principles and are not meant to be prescriptive. The Living Donor
Committee developed these recommendations with feedback and considerations from the Ethics and VCA Committees.

The Living Donor Committee offers four global recommendations:

- Prior living donors should receive priority if they are listed for transplant
  - Living donation is relatively safe, but there is still intrinsic risk, prior living donor priority offers support and assurance for the donor and donor’s family
  - This follows the initial intent of prior living donor priority, honoring the societal value of reciprocity and sending a message to the public that the system values living donors
  - The relative numbers associated with prior living donors added to the waitlist are small, with the largest group – prior living kidney donors registered to the kidney waiting list – at about 189 from April of 1994 to July 2019
- All prior living donors should receive priority for any organ needed
  - This honors the societal value of reciprocity and provides support to donors. Living donors contribute to the transplant system by donating to one waitlisted patient and enabling transplantation of another
  - Additionally recommended, if a prior living donor were to be listed for multiple organs, they should receive priority for each organ needed
- Prior living donor priority should not have a time restriction
  - The time between donation and end organ disease is highly variable and difficult to define, and without long-term outcome data available, any selected time limit would be arbitrary
  - Time restrictions are unfair to young donors, for whom lifetime risk is higher
- Prior living donors should not be valued differently based on organ donated
  - Prior living donor priority should provide foundational protections for all living donors, and living donors should not be valued differently based on their type of donation
  - Living donors make a selfless decision to put their health at risk to improve the life of another, and judgement should not be placed on what type of organ donation is more “valuable” than another
  - In discussing the inclusion of VCA living donors, the Living Donor and Ethics Committees considered:
    - The only VCA living donation in the US is uterus (20 since 2016). Although urinary tract injury is a surgical risk for uterine donors, the Committee feels there is an exceptionally low likelihood of VCA living donors needing future transplant
    - Life-saving organs vs life-enhancing – there are risks associated with all living donation procedures, and both are an act of giving an organ so someone else can benefit and as such should be treated equally

The Living Donor Committee also discussed a number of other considerations, including:

- Prior living donor priority for organ, if causal connection to organ donated – direct causal connection between organ donated and organ needed would be subjective, difficult to define, and would not honor societal value of reciprocity
- Misuse of prior living donor priority poses a very inconsequential risk, particularly considering the extensive psychosocial and medical evaluations living donors undergo
- Giving the living donor choice to receive priority would place unwarranted pressure on a living donor in need and take advantage of the selfless, giving nature of living donors. There also exists an imbalance of clinical knowledge between donors and transplant professionals.
Summary of discussion:

One member asked for the Chair of the Living Donor Committee’s thoughts on current prior living donor priority in kidney allocation, and whether prior living donors should have higher priority over 100 percent calculated panel reactive antibodies (cPRA) patients. The member continued that there are so few prior living donors, and noted that their donation to the transplant system could have contributed to their end stage renal disease. The Chair of the Living Donor Committee shared that their committee had similar discussions a few years ago, and when this question was posed to prior living donors themselves, all of them agreed that highly sensitized patients should have higher priority than prior living donors. The Chair of the Living Donor Committee also noted that there is also value in the ability of transplant professionals to let living donors and living donor families know that the transplant system will value them and their donation for a lifetime. The Chair of the Living Donor Committee expressed appreciation for the nuance in kidney allocation and respect for a decision that would allow highly sensitized candidates ahead of prior living donors in kidney allocation.

A Chair remarked that there is an understanding in the general public that prior kidney donors who need a kidney “go to the top of the list,” which is inaccurate, since there is no single “list,” and that there are other situations where certain candidates would have higher priority than a prior living donor. A heart-kidney candidate would receive a kidney ahead of a kidney-alone candidate, for example. The Chair concluded that it is important to appropriately express to prior living donors that they will be highly prioritized and are likely to be transplanted quickly. The Chair also expressed appreciation for the effort and thought used to develop these recommendations, beyond the gut reflex of support for prior living donor priority. The Chair of the Living Donor Committee thanked the Workgroup Chair, and remarked that it’s important to put aside emotional responses to this topic in order to thoroughly explore medical and ethical justifications.

One member commented that while it is easy to understand prioritization for a kidney donor needing a kidney, it can be difficult to determine the appropriate amount of priority for a prior kidney donor in need of a heart, lung, or liver. This is particularly true in cases where there are severely medically urgent patients. A representative from the Living Donor Committee pointed out that this question comes back to the fundamental values question involved in converting attributes into points and determining the appropriate relative weight of an attribute. The idea for highly sensitized candidates receiving priority, is that it is rare for these patients to match with any donor organ, and every opportunity is critical. The member added that without data on the frequency of high cPRA candidates or how prior living donors are impacted by relative priority, it is hard to compare that experience of a highly sensitized candidate with that of a prior living donor. A member referenced causality, and expressed that a living kidney donor needing a kidney should receive high priority. The member continued that the causality is less clear for a kidney donor who needed a heart transplant, and remarked that higher priority may not be as appropriate.

4. Prior Living Donor Priority Discussion and Recommendation of Rating Scale

The Workgroup reviewed the recommendations for prior living donor priority rating scale, and discussed what would qualify a candidate for prior living donor priority.

Data summary:

Recommendation: Binary (yes/no) Scale for both Kidney and Pancreas

Summary of discussion:

A Workgroup Chair agreed with the recommendation, adding that it seems very straightforward. One member suggested that the rating scale could give higher priority for prior living kidney donors than
prior living donors of other organ types, so there is some flexibility. The Chair responded that it would be simpler as a binary scale where all prior living donors were treated equally regardless of organ donated, and asked if there would be any situation where a binary rating scale for prior living donor would not be inclusive. Another member agreed, noting that it is likely better and simpler to stick with any prior living donor receives priority, regardless of organ donated.

One Workgroup Chair asked members if the current requirements for candidate physician reporting to qualify a prior living donor would be sufficient in a continuous distribution system. A member agreed, also noting that it would be important for “intended recipient” to remain the same, in the case where intended recipient issues prevent a living donor organ from being utilized with the original candidate. Another Workgroup Chair agreed.

A Workgroup member presented a scenario where a potential living donor was worked up, available, and ready to donate when the recipient received a deceased donor kidney, and asked if intention would be enough to qualify the donor for prior living donor priority. A Workgroup Chair commented that this would not be sufficient to receive prioritization. Another member agreed, noting that if a patient hasn’t had organ donation surgery, then the organ failure wouldn’t be related to donating or donation risks. It would be difficult to justify prioritization for those who did not actually donate or have donation surgery. The questioning member agreed, and pointed out that the Living Donor Committee’s recommendations stated that causality between donation and end organ disease isn’t easily defined and shouldn’t necessarily be required for prior living donor priority. A Workgroup Chair agreed, but added that the recommendations were for candidates who donated, not intended to donate. Another Workgroup Chair expressed that intention is difficult to judge, and that the donation needs to have happened. The Chair shared that potential living donors can often decide not to donate late in the process – intention is insufficient.

A Workgroup member presented a different scenario, where a potential living donor undergoes anesthesia, an incision may or may not have occurred, and the surgery cannot be carried out either due to donor or recipient instability. One member suggested reviewing the technical definition for when donation has occurred, as there is one for when transplant has occurred (first anastomosis). Another member remarked that scenario is not unheard of, adding that there is still a lot of risk for that patient even just getting anesthesia and other donation related procedures, even if the surgery cannot occur at the last minute. The Chair of the Living Donor Committee provided a donor perspective, sharing that if they left the hospital with all organs intact (including organ intended to be donated), they would have no expectation of prioritization. The Chair of the Living Donor Committee also recommended that the Workgroup have thorough discussions about causality if that reasoning will be used to underlay prior living donor priority. Both the Ethics and Living Donor Committees experienced the same dynamic of releasing causality as a rationale and a driver after more discussion and consideration.

A representative of the Living Donor Committee asked how common it was for a potential and intended living donor to be worked up and under anesthesia before a surgery was stopped. The representative continued, asking in that situation, if the surgery became complicated and the donor had related renal failure, whether prior living donor priority would be appropriate. One member shared that in their experience, living donation surgeries were cancelled due to recipient issues. The member agreed the representative’s scenario is complicated, and provided a similar scenario, such as a technical mistake in the living donor operating room that renders a kidney non-transplantable. In that case, the intent to donate is very clear, and the complications were directly caused by donation surgery. Another member agreed, noting that it shouldn’t rest on causality, but should get back to intention. The member continued, commenting that if a patient was harmed by their donation in anyway, they should get the benefit of their attempt at donation. Another member agreed.
A representative of the Living Donor Committee recommended creating some kind of appeal process for rare but possible scenarios. That way, policy doesn’t need to account for every scenario. A member agreed. Staff shared that while there isn’t currently a review board for kidney, the Workgroup will be discussing creating one as part of the Continuous Distribution project.

Upcoming Meeting

- October 1, 2021 (Teleconference)
- October 15, 2021 (Teleconference)
Attendance

- **Committee Members**
  - Martha Pavlakis
  - Rachel Forbes
  - Silke Niederhaus
  - Jim Kim
  - Abigail Martin
  - Tarek Alhamad
  - Amy Evenson
  - Arpita Basu
  - Beatrice Concepcion
  - Cathi Murphey
  - Oyedolamu Olaitan
  - Parul Patel
  - Pradeep Vaitla
  - Raja Kandaswamy
  - Jodi Smith

- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda

- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Jon Miller

- **UNOS Staff**
  - Lindsay Larkin
  - Joann White
  - Rebecca Brookman
  - Alison Wilhelm
  - Amanda Robinson
  - Ben Wolford
  - Janis Rosenberg
  - Joel Newman
  - Kaitlin Swanner
  - Kayla Temple
  - Lauren Motley
  - Leah Slife
  - Sarah Booker
  - James Alcorn

- **Other Attendees**
  - Heather Hunt
  - Aneesha Shetty
  - Vineeta Kumar
  - Angie Nishio-Lucar