OPTN/UNOS Ethics Committee
Meeting Minutes
August 17, 2017
Conference Call

Elisa Gordon, PhD, MPH, Chair
Keren Ladin, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToTraining teleconference on 08/17/2017 to discuss the following agenda items:

1. Committee Orientation
2. White Paper - Living Donation by Persons with Fatal Diseases
3. Public Comment Items from the Kidney Committee
4. Other Significant Items

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

1. Committee Orientation

The Committee Chair led an orientation for new and returning Ethics Committee (the Committee) members.

Summary of discussion:

The Chair reviewed the Committee charge and explained that the Committee does respond to requests to consider individual cases. Next, the Committee roster was reviewed. The four new members joining the Committee introduced themselves and shared why they volunteered to serve on the Committee. The Chair reviewed expectations for all members which include participating in all Committee meetings and review meeting material in advance. The Chair discussed expectations for regional representatives and explained that any materials that would be needed for a regional meeting would be provided by the Committee liaison. The schedule for the current round of regional meetings was reviewed.

The Committee has two in-person meeting each year and these meetings typically occur at the Chicago O'Hare Hilton. The Committee is scheduled to meet on October 2, 2017 and will meet for the first time at UNOS headquarters on Richmond, VA. The Committee will meet at UNOS headquarters once during each three year cycle. The Committee will have a monthly recurring web conference.

The Committee liaison explain his role with the Committee. Most of the work of the Committee is coordinated through a SharePoint site. Members will receive an announcement each Monday afternoon with a link to everything posted to the SharePoint during the previous week. Members can access these materials at their convenience. Members were asked to contact the liaison for any questions or problems with the SharePoint site.

The Chair reviewed the OPTN Strategic Plan, and the allocation of resources assigned to each goal. Ethics Committee projects typically will not have IT requirements and consequently do not have an impact on strategic alignment.

The Chair reviewed the roles of the Policy Oversight Committee and the Executive Committee of the Board.

The Chair reviewed recent and current Committee projects and noted that since 2016, all white papers require public comment.

Next steps:

None

2. White Paper - Living Donation by Persons with Certain Fatal Diseases

The Committee developed a white paper entitled Living Donation by Persons with Certain Fatal Diseases Who Meet the Criteria to be Living Organ Donors.

Summary of discussion:

This white paper is out for public comment through October 2, 2017. The white paper is on the consent agenda for the regional meetings. The white paper was presented during a national webinar on August 20th. There was one question regarding the white paper during the national webinar. The question addressed if the white paper called for a change in current policy. The white paper identifies existing policy that may need to change to facilitate living donation by persons with certain fatal diseases but the Committee would not lead an effort to change policy. Other OPTN committees could consider potential changes to existing policy.

Next steps:

Regional representatives will be notified if the white paper is pulled off the consent agenda for any regional meeting. Committee leadership will present the white paper to several committees during the public comment period.

3. Public Comment Items from the Kidney Committee

The Chair of the Kidney Committee joined the web conference to lead PowerPoint presentations for a concept paper and two policy proposals out for public comment.

Summary of discussion:

Allowing Deceased Donor-Initiated KPD Chains –

Deceased donor-initiated KPD chains has great potential to increase number of transplants.

In September 2016, the Ethics Committee sent a letter outlining the ethical parameters that should be considered for this project. The letter advised that the work group evaluate deceased donor-initiated chains considering the principle of equity and to specify how potential solutions would address concerns and be monitored and enforced. Specific concerns identified by the Ethics Committee included:

- Potential negative effects on equity in access to kidney transplantation
- Potential to deplete O-type deceased donor kidneys available for Wait List
- Unequal distribution across ethnic minority groups
- Deceased donor kidneys maybe better quality than the organ ultimately donated back to Wait List
- Potential negative impact to trust in deceased donation allocation if living donors break Kidney Paired Donation (KPD) chains and undermine return of kidneys to the Wait List

This concept paper provides three different models that could be used for deceased donor-initiated KPD Chains: An explanation of each system (copied from the public comment document) follows:

In a *candidate-driven system*, a candidate enrolled in KPD is given predetermined priority on the deceased donor waitlist in exchange for their paired donor donating. These types of exchanges

have a few defining features: one, the candidate and the paired donor first consent to a deceased donor transplant in exchange for the living donor's donation. Once consent is granted, the candidate receives elevated priority on the deceased donor waitlist for a kidney transplant. Once the paired candidate receives their deceased donor kidney transplant, their paired donor initiates a KPD exchange. This agreement is not binding and the donor can decline to donate at any time. The chain continues with a bridge donor or donates to waitlist.

In a *list exchange system*, a donor/candidate pair enters the KPD program together. The paired living donor is matched to a paired candidate to begin a chain, similar to a non-directed donor chain. The chain continues with a bridge donor or donates to the waitlist. After the living donor donates, their paired candidate receives elevated priority on the deceased donor waitlist.

In a *donor-driven system*, a deceased donor kidney is redirected from the waitlist allocation for placement with a KPD program. Criteria would be set for which deceased donors could be redirected in this manner. The deceased donor's information would be entered (transferred) to a KPD system. A match would immediately be run with the donor's information and a chain identified. A paired candidate receives the deceased donor transplant in a similar time frame from standard deceased donor allocation. The paired donor and rest of the chain moves forward with standard KPD timing and logistics. The chain continues with a bridge donor or donates to waitlist.

If a preferred model is identified based on public comment the Scientific Registry of Transplant Recipients will be asked to provide modeling.

A Committee member asked if there are data on the rate of living donor that do not donate after their pair receives a transplant. The Kidney Committee Chair responded that a recent study revealed that the recidivism rate is very low, and will provide the study for members to review.

Other specific concerns or questions from members included:

These concepts could have a negative effect to O-donors (and B donors) on the Waitlist.

Would the organ blood type that initiates a chain and the organ blood type that goes back to the Waitlist need to be the same? The Kidney Committee Chair responded that this would be an important question to address with modeling.

What does increased priority mean? The Kidney Committee Chair responded that this will need to be determined.

With regard to candidate-driven model, minorities have fewer potential donors. This model could give priority to candidates with living donors over candidates without living donors to participate in KPD.

Some of the models may make the most disadvantaged groups even more disadvantaged.

The List Exchange Model may be preferable model because the living donor donates first which ensures that a living donor donates.

It will be important to consider if an O kidney is taken from a deceased donor to initiate a chain, several O candidate could be transplanted and O candidates may benefit overall even if an O organs does not go back to the Waitlist.

<u>Next steps:</u>

The Committee will prepare a response regarding this concept paper.

Improving Allocation of En Bloc Kidneys

The Chair of the Kidney Committee explained that this proposal was not supported by the OPTN/UNOS Board in June 2017. Currently there is no OPTN policy addressing allocation of en block kidneys. DonorNet overestimates KDPI score for en bloc kidneys which could potentially screen medically suitable candidates off the match run. The proposal includes five solutions including:

Mandatory en bloc allocation based on donor weight:

- Allocate en bloc kidneys on KDPI 0-20%
- Mask KDPI score in en bloc kidney allocation
- Center must report to UNOS if they are willing to accept en bloc kidney in order to receive en bloc offers
- Kidneys allocated en bloc can be split at the surgeon's discretion if could be transplanted as two single kidneys
- If split must release second kidney according to Policy 5.9

If en bloc kidney are split offering the second kidney back to the list aligns with current policy and should help ensure transparency and prevent gaming. The Kidney Committee is seeking specific feedback regarding the most ethical approach to managing the second kidney in a split pair?

A member asked why 18 kilograms was selected as the cut off for the policy. The Kidney Committee Chair explained that using 18 kilograms will allow hospitals that perform en bloc transplants to continue their current practice. If a lower weight cutoff was used, hospitals would lose offers for en bloc kidneys.

Next steps:

The Committee may prepare a response regarding this proposal.

Improving Allocation of Dual Kidneys

The Chair of the Kidney Committee provided a quick overview of this public comment item. She explained that discard rates for high KDPI kidneys is at or above 50%. Under this proposal Policy 8.6 (Dual Kidney Allocation would be updated to promote more efficient placement of high KDPI kidney.

A member asked her to explain the difference between en bloc and dual kidneys. She explained that en bloc kidney would be offered to small pediatric candidates and dual high KDPI kidney would be an option for adult candidates.

Next steps:

The Committee may prepare a response regarding this proposal.

4. Other Significant Items

The liaison will determine dates and times when leadership are available and then poll members to determine potential new dates for a recurring monthly meeting.

The Committee will meet at UNOS headquarters in Richmond, Virginia, on Monday, October 2, 2017. This will be the first time the Committee will meet at UNOS headquarters. The current plan is for the Committee to meet at UNOS headquarters once every three years.

Upcoming Meeting

- September 21, 2017