OPTN/UNOS Living Donor Committee
Meeting Minutes
September 13, 2017
Conference Call

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Introduction

The Living Donor Committee met via Citrix GoToTraining teleconference on 09/13/2017 to discuss the following agenda items:

1. Deceased Donor-Initiated Kidney Paired Donation (KPD) Chains Project
2. Living Donation by Persons with Certain Fatal Diseases Who Meet the Criteria to be Living Organ Donors

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

1. Deceased Donor-Initiated Kidney Paired Donation (KPD) Chains Project

The Chair of the Kidney Committee lead a PowerPoint presentation on a concept paper addressing Deceased Donor-Initiated Kidney Paired Donation (KPD) Chains

Summary of discussion:

The Kidney Committee Chair explained that this a goal one project under the strategic plan intended to increase the overall number of transplants. Studies show that kidney paired donation has a great potential to increase transplant volume. Although KPD chains may ultimately end in donation to the waitlist, deceased donor kidneys are currently not used to begin chains. Using deceased donor kidneys to initiate KPD chains could greatly expand the number of transplants overall as each deceased donor kidney could unlock multiple transplant opportunities. Deceased donor-initiated chains may also better utilize kidneys to maximize the potential of KPD donors and deceased donors to increase the overall number of transplants.

The Kidney Committee's Deceased Donor Chains Work Group began meeting in October of 2016 with the goal of developing and proposing amendments to Kidney Allocation System (KAS) that allows deceased donors to initiate chains. The workgroup anticipates that this project will be of great interest to the transplant community, so it opted to publish a concept paper during this public comment cycle. The concept paper includes an overview of three different models that could be used to allow deceased donors to initiate KPD chains.

The work group is currently reviewing recent literature and discussing the pros and cons of each model. If a preferred model is identified through public comment, the Work Group will then begin discussing how to develop policy and will request modeling from the Scientific Registry of Transplant Recipients (SRTR).

The first concept discussed was the Candidate Driven Model. Under this model the candidate and the paired donor consent to the candidate receiving a deceased donor kidney transplant in exchange for donor initiating a chain. The candidate receives additional priority on the deceased donor Waitlist for a kidney. A deceased donor kidney is offered to candidate and if he or she accepts, he or she would be transplanted. It is not until after candidate is transplanted that donor's KPD program activates the donor in a match run. Once they do so, the donor is matched and continues the chain that started with the deceased donor. The donor at the end of

the chain either donates to the waitlist or continues the chain in another match run as a bridge donor.

The next model discussed was the list exchange chain model. Under this model the donor donates first to initiate a KPD chain. The chain continues until the donor at the end either donates to the Waitlist or bridges to continue the chain. It is not until after the donor donates that the candidate receives increased Waitlist priority, is offered a kidney and transplanted. This model is the only one that has historical precedent as three list exchange chains were performed under a variance in Region 1 before implementation of KAS.

The last model presented was the donor-driven model. After the paired donor and candidate provide their consent, a deceased donor kidney is *redirected* from Waitlist allocation to a KPD program. The candidate is registered as a KPD participant in conjunction with the donor, is a matched with this kidney. The candidate accepts the offer and is transplanted. The donor donates after the candidate is transplanted. The chain continues until the last donor either donates to the waitlist or bridges to continue the chain in another match run.

The presentation concluded with several specific question for consideration:

- Which model(s) presented in the Concept Paper are preferred? Not feasible?
- Are there other methods for using deceased donor kidneys to initiate KPD chains that the workgroup should consider?
- How can policy be developed so as to protect vulnerable or disadvantaged populations (e.g. blood type O, pediatrics, minority populations, etc.)?
- Should policy apply to all KPD programs nationwide, or be more limited in scope?
- Should policy be tested via a variance or pilot, or follow the normal policy development process?

After the presentation concluded the Kidney Committee Chair offered to address questions. Living Donor Committee members provided the following questions or comments, and responses from the Kidney Committee Chair are included.

Based on available information, would one of the three models be expected to results in more total transplant? We don't know at this time, if one of the models is preferred during public comment it will be modeled by the SRTR. The current expectation is that only one of the options would be modeled by the SRTR. To date, public comment has favored the list exchange model because the donor donates first and consequently cannot break the chain.

A member questioned if compatible pairs could participate. At this time, the UNOS KPD system does not permit compatible pairs, but other KPD systems in the country do accept compatible pairs. The question is still being investigated. The UNOS KPD system is resulting in approximately 50 transplants per year. The Kidney Committee Chair commented that a model(s) could be tested through a small trial or through some type of policy variance.

Several members commented that they were concerned because minority and low income candidates are less likely to have a living donor and consequently are already disadvantaged. All of the proposed models would give priority to candidates paired with a living donor. The Kidney Committee Chair reported that this has been a common concern with the concept paper and modeling should help address this concern. She noted that the proposed models could decrease the number of candidates on the Waitlist and could decease time on the Waitlist.

A member raised a concern regarding the list exchange model. For a highly sensitized candidate with a living donor it could be risky for the donor to donate to the list because it might not be possible for their highly sensitize candidate to find a match. Giving a highly sensitized candidates priority on the Waitlist would not guarantee a transplant. The Kidney Committee

Chair commented that more information is needed to help address some of these questions and future modeling should help. A member commented that the proposed models could pull better quality kidneys from the Waitlist compared to the kidneys that may be returned to the Waitlist at the end of a paired exchange.

A member suggested that a single model may not fit all donor-recipient (D-R) pairs. For example, many D-R pairs in KPD sit for a long time because the recipient is highly sensitized only to have the possibility of KPD end because the recipient gets a deceased donor organ through the new kidney allocation system's prioritization of 98-100% PRA candidates. These candidates don't necessarily need more points and if their living donor donates first, they've sacrificed their living donor with no guarantee as to when a compatible deceased donor might come along. One option might be a hybrid model that allows some lesser degree of "bonus" for these sensitized recipients since they already have a huge point advantage for their PRA. Then, there is some advantage to having the living donor participate, but if the living donor were to back out after the recipient's deceased donor transplant, it's a minor insult to the system, because the candidate would like have received a deceased donor organ.

D-R pairs *not* advantaged by major PRA points might chose to enter the deceased-initiated KPD program through another path where they get more points in exchange for the pair's participation. In this pathway, perhaps the donor initiates the chain but because the recipient is not sensitized, they should have a reasonable chance of getting transplanted soon. Perhaps they get points that would place the candidate higher on the local wait list.

Next steps:

The Living Donor Committee will prepare and post a response to this concept paper.

2. Living Donation by Persons with Certain Fatal Diseases who meet the Criteria to be Living Donors

The Chair of the Ethics Committee lead a PowerPoint presentation on a white paper addressing living donation by persons with certain fatal diseases who meet the criteria to be living organ donors

Summary of discussion:

The Ethics Committee Chair explained that there have been anecdotal and published reports that reveal transplant hospitals have been reluctant to approve persons with certain fatal diseases for living donation due to concern over violating informed consent policy requirements and because all living donor deaths within two years of the organ donation date must be reported to the OPTN through the Improving Patient Safety Portal.

The white paper out for public comment addresses the scenario of an individual:

- Who wishes to be a living organ donor
- Who has a progressive, incurable, chronic disease that is fatal and will ultimately be terminal
- Whose fatal disease would not put the individual at unreasonably high risk, as determined mutually by the transplant hospital and the living organ donor, for an adverse outcome after donating
- Whose fatal disease has not led to substantial reduction in the medical quality of the organ to be recovered and transplanted

The Ethics Chair explained that there is a Danish study addressed in this white paper and there are other recent articles cited in the white paper about persons with fatal disease who wanted to donate an organ but were refused the opportunity to do so.

The first article reported the case of a man with Amyotrophic Lateral Sclerosis who wanted to be a donor and the second article reported the case of a woman with Multiple Sclerosis who wanted to be a living organ donor. In both cases the hospital involved did not approve the potential donor for living donation.

Several ethicists who serve on the Ethics Committee reported that they have been consulted on similar cases and in each case the hospital ultimately did not approve the candidate for living donation.

Based on these published and anecdotal reports and experience of Ethics Committee members, the Ethics Committee determined the transplant community may need guidance regarding how to handle potential living donors with certain fatal diseases who meet the criteria to be living donors.

Living organ donation by persons with certain fatal diseases is supported by the ethical principles of autonomy, beneficence, justice, and nonmaleficence and the white paper includes an analysis of each these principles.

Based on its analysis of these principles, the Ethics Committee opines that individuals with certain fatal diseases who express interest in donation should be considered for living donation. The Ethics Committee recommends that some elements of current OPTN Policies for living donor informed consent, psychosocial and medical evaluation and follow-up should be modified to accommodate the circumstances of individuals with certain fatal diseases who wish to be living organ donors. The Committee recommends that other committees could determine which subset of LD policies should be applicable to potential living donor with certain fatal diseases.

The Ethics Committee recommends that the OPTN should work with the transplant community to determine which policies for living donor informed consent, psychosocial and medical evaluation and follow-up should not be necessary or appropriate for individuals with certain fatal diseases who wish to be living organ donors.

The Ethics Committee further recommends that the OPTN should take steps to remove disincentives and undue scrutiny of transplant hospitals that undertake the recovery of organs from individuals with certain fatal diseases who wish to be living organ donors.

After the presentation concluded the Ethics Committee Chair offered to address questions. Living Donor Committee members provided the following questions or comments and responses from the Ethics Committee Chair are included.

A physician serving on the Committee commented that she supported this concept overall but was concerned that potential living donors with fatal diseases may have unexpected complications (e.g. unable to be extubated) after donation surgery. She commented that there is limited experience with elective surgeries for potential living donors with Chronic Obstruction Pulmonary Disease (COPD) or ALS. Donating an organ could negatively impact progression of the fatal disease. Potential living donors with fatal disease may need additional protections for informed consent and medical evaluation.

A member questioned why this white paper was categorized as a goal one (increase the total number of transplants) under the strategic plan. This member commented that in her opinion the number of potential new organs available for transplant would be very small.

A member questioned if stakeholder groups had been contacted regarding public comment for the white paper. The Living Donor Committee liaison responded that ALS and Muscular

Dystrophy Societies and a Catholic Bioethics organization had been contacted to request feedback on the white paper.

A member questioned if a living donor with a fatal disease who donates an organ could also be a deceased donor and questioned if waiting for deceased donation would result in more organs for transplant. Another member commented that not allowing someone with certain fatal diseases to be a living donor would violate the autonomy of the potential donor especially is the potential donor wants to die at home.

A member was concerned that allowing organ donation by persons with certain fatal disease could erode public trust in the transplant system. A member was concerned that living donors with certain fatal disease who donate an organ and die within two years of their donation date related to progression of the fatal disease would need to be reported to the Organ Procurement and Transplantation Network (OPTN) as a living donor death.

A member question the use of the phrase “right to refuse life support after donation” and how it would be different from assisted suicide or imminent death donation. The Ethics Committee liaison responded that imminent death donation requires surrogate consent, under the concept addressed in the white paper the living donor provides informed consent.

Next steps:

The Living Donor Committee will prepare and post a response to this white paper.

3. Other Significant Items

Committee members were encouraged to submit individual comment for the proposals considered during the meeting.

Committee members were encouraged to arrange their travel as soon as possible for the full in-person committee meeting on October 23rd in Chicago to help keep the cost of flights as low as possible.

Upcoming Meeting

- October, 2017