

Carl Berg, M.D.
President, Board of Directors
OPTN/UNOS
700 North 4th Street
Richmond, VA 23218

December 4, 2014

Dear Dr. Berg:

We appreciate the opportunity to provide comments regarding the proposal for informed consent for kidney paired donation. Having successfully organized over 1,200 paired exchange transplants, our experience in KPD gives us a unique perspective to add value in shaping policy in this vital growth area in kidney transplantation.

1) "Inform KPD participants of... logistics of the KPD program's matching process, including prioritization information..." (page 1 and throughout the proposal)

The challenge with the wording of this requirement is that it is very broad. The logistics of the NKR matching process, including prioritization information, is immense. The logistics and matching systems consumed over 20,000 man hours of systems development and could fill the pages of several text books.

We recommend this be narrowed to focus on the material risks and benefits of KPD without placing an undue burden on transplant programs.

2) "Inform KPD participants of... consequences of shipping kidneys." (page 1 and throughout the proposal)

It is not clear what the "consequences of shipping kidneys" is intended to cover. If it is intended to focus on KPD outcomes, the latest research indicates there is no correlation between graft survival and shipping distance or CIT. In fact, NKR graft survival rates exceed the average U.S. living donor graft survival rates. Additionally, the superior NKR outcomes include more highly sensitized patients which generally correlates with lower graft survival.

We believe the foremost consequence of shipping kidneys is the potential for real time swap failures (RTSFs). The NKR has experienced 6 RTSFs while facilitating 1200 transplants which works out to about one in every 200 KPD transplants. It is worth noting that none of these RTSFs were caused by shipping problems. The most common scenario are donors and recipients who are medically unable to complete surgery (e.g. patient experiences medical complications once surgery has commences and surgery must be aborted) requiring the kidney to go to a backup candidate on the wait list and not the KPD patient, or preventing a donor from donating, leaving one KPD patient without a kidney.

We recommend the "consequences of shipping kidneys" be narrowed to focus on the risk associated with a shipping problem which can cause a RTSF.

- 3) **“As defined by OPTN/UNOS policy, an exchange is a set of KPD matches that form a chain, a two-way exchange, or a three-way exchange.” (page 3)**

This definition implies that a 4-way or larger loop would not be considered an exchange.

We recommend that the defined term “human organ paired donation” from the Charlie Norwood Living Organ Donation Act be used to define an exchange.

- 4) **“The JSWG recommended each KPD program prioritize candidates in the event of a failed exchange... The Kidney Committee believed this requirement to be too prescriptive, as it would have required all KPD programs to prioritize the candidates in some way.” (page 3-4)**

We support the JSWG’s recommendation that “each KPD program prioritize candidates in the event of a failed exchange.” Having successfully resolved 6 failed exchanges (i.e. RTSFs) the NKR has witnessed the stress and anxiety inflicted on patients, donors and transplant personnel when the “impossible scenario” collides with an exchange. The inability of a KPD program to effectively deal with a failed exchange has the potential to bring the growth of KPD transplantation to a grinding halt. One can only imagine the headlines, lawsuits and suffering created from a situation where the paired donor has donated a kidney but the loved one never received the exchange kidney.

We recommend that the original JSWG language be retained requiring all multi-center and single center KPD programs to have a publicly disclosed policy for prioritization in the event of a failed swap. Anything less could jeopardize the growth of KPD and the great hope it provides for so many ESRD patients.

- 5) **“...lack of data on loss of living donor kidneys due to shipping... there is a 1-2% loss of shipped deceased donor kidneys, and it is possible that loss of kidneys from living kidney donation will increase.” (page 5)**

The NKR has shipped approximately 1,000 kidneys and has not lost a single kidney due to a shipping mishap. It is possible that a shipping problem could occur in the future, which is why the NKR continues invest in GPS technology and organ tracking systems. Further, the NKR’s RTSF policies (see #4 above) are critical to protecting patients against a lost kidney in the event of a shipping mishap.

We recommend that all KPD programs publicly disclose, on a quarterly basis, all failed exchanges including kidneys lost due to shipping. This historical data should be utilized in the KPD informed consent process. The NKR discloses this information in its Paired Exchange Results Quarterly Report which is posted on the NKR web site.

We recognize that there is less lead time to organize the shipment of deceased donor kidneys but we recommend that the OPTN implement GPS technology and enhanced tracking systems similar to what the NKR employs to attempt to reduce the loss rate of shipped deceased donor kidneys.

6) **“The recovery hospital informs the donor... about all CMS outcome requirements not being met by recipient hospital” (page 6)**

Disclosing “all CMS outcome requirements that are not being met” to the donor is overly broad and generally of little interest to a paired donor who is primarily interested in helping their loved one achieve a transplant. It will also be difficult for recovery centers to divulge information related to unmet CMS requirements because this information is very sensitive. When CMS attempted to require something similar related to the Living Donor Services Guidelines, it was met with significant pushback from transplant hospitals.

We recommend eliminating this requirement.

7) **“How the KPD program determines whether a chain ends with a bridge donor” (page 11)**

Determining when a chain ends with a bridge donor is a complex and dynamic process which may not be relevant to donors and would be very difficult to fully explain.

We recommend changing this requirement to focus on how transplant centers should select donors to be bridge donor candidates in order to minimize broken chains.

8) One key item missing from the informed consent proposal is donation insurance. The NKR purchases donation insurance for all NDDs who start NKR chains. It is our strategic ambition to expand donation insurance to all paired donors. This insurance coverage is uniquely important to KPD because the donor does not know the recipient but is relying on the recipient’s insurance (or the recipient individually if the recipient loses health insurance coverage) to reimburse post-donation complications. This is further complicated by the fact that the donor is prohibited from contacting the recipient without the recipient’s consent.

Imagine a scenario where the KPD donor donates and the recipient loses health insurance a month later due to a job loss. This is followed by the donor having a major post-donation complication which is not reimbursed because the recipient no longer has health insurance. In this situation, the donor could be put in a position where they need to initiate legal action against the recipient to recover donor medical costs related to the complication. One can only imagine the headlines, lawsuits and suffering created from this type of a scenario.

We recommend that all KPD donors are informed about donation insurance (cost of the policy is approximately \$500) and we encourage all KPD transplant hospitals to either, 1) purchase donation insurance for KPD donors or, 2) provide medical services to KPD donors

for post-donation complications at no cost. Neither of these approaches is without precedent as several NKR member centers are already providing donation insurance and several others are covering post-donation complications at no cost.

Thank you again for the opportunity to provide feedback on the proposal for informed consent for kidney paired donation. Please let us know if you have any questions.

Sincerely,

Garet Hil

Chief Executive Officer

National Kidney Registry