

The Legal, Logistical, and Regulatory Issues Posed by Using Deceased Donors to Start KPD Chains

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Disclosure

I have no financial relationships to disclose relevant to my presentation and my presentation does not include discussion of off-label or investigational drugs

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Polling question: Should deceased donor organs be diverted to start KPD chains?

A. Yes, the potential benefits outweigh the risk of increasing disparity in access to organs among vulnerable populations

B. No, the potential for increased disparity, effects on public trust and the uncertain benefit make this approach unacceptable

Regulatory Framework

- National Organ Transplantation Act 1984
- Organ procurement and Transplantation Network Final Rule 1999

NOTA 274 b.2.A.ii

The Organ Procurement and Transplantation Network shall establish a national system.....

“in accordance with established medical criteria”

.... match organs and individuals included in the list

NOTA 274 b.2.B

The OPTN shall establish....

“medical criteria”

....for allocating organs

Access to deceased donor organs based on whether or not the recipient has an incompatible living donor is NOT “established medical criteria”

FR 121.7.a

An OPTN member procuring an organ shall operate the OPTN **“computer match to identify and rank potential recipients for each cadaveric organ”**.

The system must be programmed to include KPD candidates. Programming must include criteria for selection among multiple potential KPD recipients or multiple KPD programs

FR 121.8 The OPTN shall develop policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

- Shall be based on sound medical judgement
- Seek to achieve the best use of donated organs
- Shall be designed to avoid wasting organs, to avoid futile transplants
- Shall not be based on the candidate's place of residence or place of listing

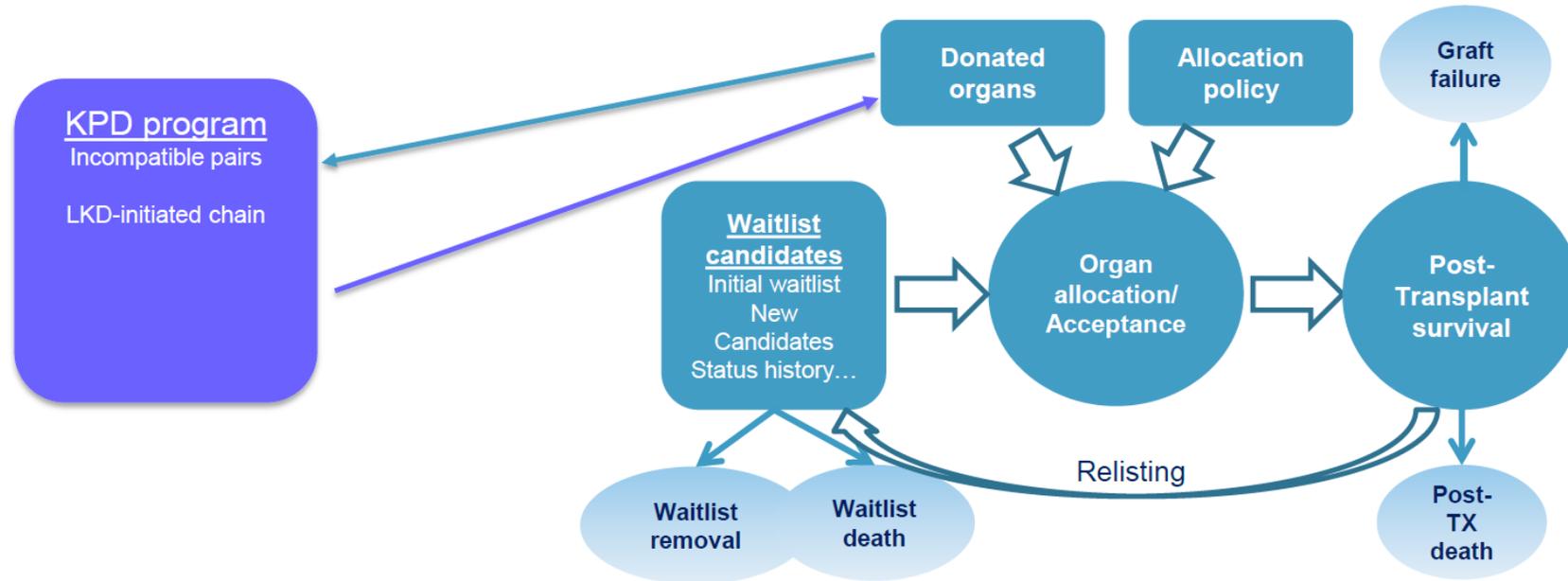
FR 121.8.b

“Allocation policies shall be designed to achieve equitable allocation of organs among patients...through objective and measurable medical criteria...distribute organs over as broad a geographic area as feasible”

Living donation is inherently inequitable, allocation policy would be based on a utility measure, rather than medical criteria, and would not be distributed over as broad an area as possible

“Best use” versus “equitable allocation”

KPSAM/KPD interaction



SRTR Modeling

- Need to make assumption without being based on data
- Impact of allocation changes is limited to 1 year in scope
- Impact on ABO:O DDWL candidates, and those less likely to be enrolled in KPD (minorities) will be difficult to detect due to the small size of KPD versus DDWL (< 0.5% of DDWL is in KPD N=454)
- Full KPSAM/KPD integration would take about 1 year

SRTR modeling capabilities points of uncertainty

- Willingness of dually listed to accept an offered DD over continuing to wait
- Willingness of those on the DD list to accept an LD from the KPD pool
- In list exchange: willingness of LDs to donate before candidate receives an organ
- Renege rates
- How much would KPD programs grow if KPD and DDWL interact

NKR public comment

- NKR median wait time from pair activation to transplant 1.7 months (n = 2200+)
- Limited impact on preponderance of pairs
- Some may be amenable to receiving a deceased donor kidney (remember that people enter KPD with the goal of receiving a living donor kidney) unfavorable blood type pairs and 99%+ pairs
- Currently NKR has 222 pairs waiting. 12 matchable pairs waiting more than 12 months.

NKR cont

- All of the 12 are O recipients with A or AB donors Transplanting these from the DD pool would have minimal impact on the number of KPD transplants and would disadvantage O's on the DD list
- NKR has 48 “unmatchable pairs waiting more than a year. 45 are cPRA > 99% Half of these are unfavorable blood type combinations
- Estimates that 20 – 100 more transplants per year

Utility Questions

- The potential increase in transplants may be over-estimated because it assumes that people in the chain would never be transplanted through conventional KPD or the DD pool. What the proposals really do is decrease waiting time for chain participants but not necessarily increase the number of transplants

Logistical Questions

- Which organs will be considered for re-direction into a chain
- Recipients will want a high quality organ, comparable to an LD kidney
- Removing the high quality O kidneys further disadvantages O groups
- Will a locally active KPD program introduce geographic disparity?
- Return an O kidney to the same OPO as the DD that initiated the chain

Logistical complexity

- Need more than one model a blended model?
- Candidate driven for high cPRA
- List exchange for less sensitized
- One size doesn't fit all

Issues

- Could reduce the pool of deceased blood type O and B kidneys available for blood type O and B patients on the list
- The DD organ used to start the chain might be of better quality than the organ returned to the DD pool
- There is incentive for the KPD program to arrange swaps to retain the best organs for the chain participants. The pair with the low quality donor would be put at the end of the chain
- Minority candidates are less likely to have living donors and would be disadvantaged in this system.

UNOS ethics committee

- Concerned about the O's
- Concerned about the quality of the kidney returned to the list
- African Americans have fewer living donors: could reinforce existing historical disparities in access to the DD list
- Could negatively impact trust in the system, especially if donors fail to follow through with donation (model dependent)
- “The Committee holds that in the currently proposed models, the principle of utility does not seem to outweigh the principle of equity

Polling question: Is there a path forward?

- A. Just do it
- B. Do a limited pilot and monitor the results
- C. Develop and assess more robust modeling prior to any decision
- D. Equity concerns outweigh utility arguments and this should not be pursued.
- E. Amend NOTA

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