



December 22, 2010

Jon H. Sutton, MBA Manager, State Affairs American College of Surgeons 633 North Saint Clair St Chicago, IL 60611

Re: AST/ASTS RESPONSE TO CEJA REPORT 6-1-10 Non-simultaneous, Non-Directed Living Organ Donation

## Dear Mr. Sutton:

Thank you for contacting the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) for input on non-simultaneous and non-directed living organ donation. The report of the Council on Ethical and Judicial Affairs on Altruistic Donation is overall timely and, for the most part, acceptable. The authors of the CEJA Report should be commended for their thoughtful approach to living donation from altruistic and anonymous donors. The AST Kidney-Pancreas Committee and ASTS Ethics Committee have comments in three main areas for consideration: general information, allocation models, and donor autonomy/ethics.

## General Information

- Most of the information presented focuses on ABO incompatible situations, but paired donation is relevant for cross-match positive cases as well.
- Recommendation 1c is particularly problematic in that it is both vague and strongly worded; if the intent is to avoid futility, it should be so stated. There will always be risks to the donor that are unexpected; the best we can do is to relate these potential risks for their consideration to balance against the potential benefits.
- Recommendation 2 should explicitly state that it is a violation of federal law for a donor to accept payment in exchange for a solid organ
- Recommendation 1bii dealing with minors is too permissive in this vulnerable population which require stronger safeguards than are currently written in the report.
- The recommendation for a follow-up database is essential, but should be accompanied by a funding mandate to CMS
- It is suggested that the first two lines of page 6, edited out of the CEJA draft, be put back in; it would be advisable to re-examine the impact of a change on the ethical considerations at hand.

## Allocation Models

- There is some concern that Recommendation 3c would restrict the ability to create chains
- While it is correct that there is currently no accepted model for allocating organs from nondirected living donors in place, it may be important to note that UNOS is currently working on a proposal of a sociocentric allocation of non-directed living donor organs.

- The description of the donor-centric model arguably undermines the autonomy of the donor; this is especially true in the case of a knowledgeable donor who may want to make decisions based on a center's outcomes.
- Recommendation 3b: it is not clear what "unreasonably disadvantage others on the waiting list" means. The issue of public solicitation for organs, something that undermines the allocation process does not belong to this section.
- The authors attempt to show that the pros and cons of paired donation work towards disadvantaging blood type O patients and term this "unethical". We believe this is stated too strongly. Patients with O blood types already are disadvantaged. Further, it presupposes that the current method of allocating organs by the OPTN is the best possible method and this may not be the case. It may be clearer to refer to the "special situation" where paired donor list exchange may impact the waiting time of blood group O patients.

## Donor Autonomy and Ethics

- The authors state that a donor may have difficulties backing out in paired donation because of prospective matching to a third party. If the premise is that because there has been a match done, there is no recourse but to continue on, this is not necessarily the case. The most compelling reason to withdraw is the autonomy of the donor.
- We need to continue to maintain the right of autonomy of donors; we may not be able to dictate or restrict to whom an organ is donated if done with genuine altruism, This may ultimately hinder the efforts of these individuals.
- We agree strongly that non-directed donors must be allowed to withdraw at any point in the process. If this type of donor is initiating a chain, then the chain simply would never begin. The authors should consider a recommendation that non-directed donors should only initiate rather than perpetuate or terminate a closed chain because of their potential (and supported) withdrawal.
- Page 2, line 45-49 is the section that discusses reasons for not proceeding with donation ("truthful or otherwise"); in this regard, the altruistic non-directed setting is not different from the altruistic directed setting (typical LRD).
- Non-traditional donors may well know the results of their donation; such meetings are often made with mutual consent through a third party intermediary.
- Donor autonomy is implicit in many of the recommendations; perhaps it could be made more explicit in several areas.

Please let us know if you have any questions or require additional information. We can be reached via 856-439-9986 or 703-414-7870 respectively.

Sincerely,

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