To: OPTN OPO Committee

From: American Society of Transplantation and American Society of Transplant Surgeons

Re: Changes to DCD Model Elements

Date: November 23, 2010

Thank you for inviting comments from the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) on proposed changes to the Model Elements for Controlled Donation after Circulatory Determination of Death. Members of the ASTS Executive Committee and AST organ specific committees were solicited for their thoughts regarding the proposed changes. The respondents were generally supportive of the changes and specific comments/recommendations are outlined below.

Overall Comments

There is strong support for the change from Donation after Cardiac Death (DCD) to Donation after Circulatory Determination of Death (DCDD). This change has been advocated by Bernat as a way of maintaining the ethical standard of the Dead Donor Rule while still permitting heart transplantation from non-heart beating donors.

A majority of respondents noted the importance of the OPO's role in educating donor hospitals about DCDD donation as there was strong feeling that donor hospitals frequently misunderstand the process of DCDD donation.

Suggested Revisions

1. In the second paragraph of the Introduction – It is disingenuous to say that it's "not prescriptive" while also saying that the policy sets minimum requirements for what must be included in the protocols.
2. Under A. Agreement – It is confusing to assume that the "responsibilities" of hospitals are different from the "requirements". Perhaps this statement should be made into two sentences. Is there a difference between "critical" access hospitals and "crucial" access hospitals? Hospitals are not required to have a DCD protocol. Even the joint commission standards permit hospitals to simply have a statement that they do not wish to do DCD, therefore UNOS can't require a hospital protocol just because the OPO has a protocol.
3. Under B. Protocols – OPOs need to simply follow UNOS policy, so why comment here on organ placement?
4. Under C. Suitable Candidate Evaluation – To state "aged newborn to DSA's defined upper age limit if applicable" is superfluous; suggest deletion.
5. Under D. Consent/Authorizations, in #1 – does not make sense to have a statement about this as OPOs and hospitals are required to follow whatever is contained in their state's UAGA.
6. Under Withdrawal of Life Sustaining Medical Treatment/Support/Patient Management:

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- In the first paragraph – can't recommend a timeout when the policy itself says that it includes required minimum elements. Additionally, the "initiation of the withdrawal" is awkward and in some ways contradictory; it should change to "beginning withdrawal".
- In the second paragraph – it is suggested that OPO personnel may be present for the withdrawal, as distinguished from transplant center personnel. This is routine practice as hospital staff does not routinely track BP, respirations, etc., after extubation. This issue has been discussed extensively with CMS and they have acknowledged that OPO staff may be present.
- The fourth paragraph should be moved to the first item under this section as it is the thing that occurs first in the process.

7. F. Pronouncement of Death:
    - This section may be too vague in the description of standards for waiting time between the pronouncement of death and beginning of organ recovery. A modification to the text that the donor hospital policy should be in accordance with recommended national standards (e.g. those of the Institute of Medicine's, ASTS or Society of Critical Care Medicine) was suggested. While it is recognized that this area is controversial, lacking in empiric data and local practices of OPO need to be respected, the acknowledgement of national standards would improve the public's trust that DCDD donation is adherent to the Dead Donor Rule.
    - In the first paragraph, the difference between circulatory and cardiac death should be defined. Why is the clause "without resuscitative efforts" needed? Death can occur in the absence or presence of these efforts and it seems a given there are no resuscitative efforts in this situation.
    - In the second paragraph, autoresuscitate should be changed to "does not return". Additionally, this paragraph and the last paragraph are similar.

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