



Concerns Over Changes to Guidelines on Organ Donation After Death Department of Health and Human Services (HHS) and Grantee Proposed Changes Summary and Discussion of Changes

Background:

The Organ Procurement and Transplantation Network (OPTN):

The OPTN is an organ transplant network established by the U.S. Congress under the National Organ Transplant Act of 1984 (NOTA). The act called for the Department of Health and Human Services (HHS) to coordinate the network through a contract with a private, non-profit organization.¹ The United Network of Organ Sharing (UNOS), a non-profit organization based in Richmond, Virginia, was first awarded the OPTN grant in 1986 and has continued to win the award since that time.

A large aspect of the contract involves the coordination of the national organ donor list. In addition UNOS also has oversight of policy development, monitoring and enforcement for the OPTN. One of their major goals of the group and contract is to increase the supply of donated organs available for transplant.

Through a federal rule effective October, 2000 http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl, binding policies may be written and voted upon by OPTN/UNOS Board and approved by the Secretary of HHS. These policies are binding to member groups of OPTN which includes 257 transplant hospitals and 58 organ procurement organizations (OPO), essentially all of the major players involved in organ transplants in the United States.
<http://optn.transplant.hrsa.gov/optn/history.asp>

The OPTN/UNOS Board issued “Model Elements” in 2007² that require participants to consider various issues related to organ donation in their protocols. The Model Elements were recommendations/guidelines for transplant hospitals and OPO’s consideration.

Problem:

UNOS/OPTN is currently in the process of revising what since 2007 have been “Model Elements” (i.e., guidelines) but will soon be binding “Requirements” for OPTN members on the controversial topic of donation after cardiac arrest (DCD). Originally posted on March 11, 2011 through June 10, 2011, on the HRSA website, many in the organ donation

¹ <http://optn.transplant.hrsa.gov/optn/>

² http://optn.transplant.hrsa.gov/policiesandBylaws2/bylaws/OPTNByLaws/pdfs/bylaw_167.pdf

community were not aware of the proposed revisions until a recent media article in the Washington Post. http://www.washingtonpost.com/national/health-science/changes-in-controversial-organ-donation-method-stir-fears/2011/09/15/gIQAlY9agK_story.html. The Board will vote to accept or reject the new requirements at a board meeting in Atlanta on November 14th and 15th, 2011.

Donation After Cardiac Arrest (DCD):

What is donation after death, and how is “death” defined? Death has been defined in terms of cardiac death. “DCD is an organ procurement procedure that relies on the declaration of death being made based on a lack of cardiopulmonary function (i.e., the heart and lungs stop functioning). These patients have suffered a severe neurological injury from which they most probably 1) will not regain any substantial and meaningful recovery and 2) will not proceed to brain death.”³

Major Concerns with OPTN DCD Proposed Requirements:

1) Wait Period following time of death.

The current UNOS policy holds that DCD is implicitly linked with a wait period of at least two minutes to assure “irreversibility” of death. Death is defined as the “irreversible cessation of circulatory and respiratory functions” (p. 10, F: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf). “Irreversibility” is further defined in two categories: 1) in clinical situations where death is expected, irreversibility is “the period of observation necessary to determine that circulation will not recur spontaneously (auto-resuscitation) may only be **a few minutes.**” (p. 11: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf) “In cases where life-sustaining therapy is withdrawn, irreversible cessation does not return **after two minutes of cessation of circulation.**” (p.11: http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf).

The new Requirements delete the references to “irreversibility” that is in place in the Model Elements. Therefore, any period of waiting after declaration of death is deleted. Instead the following language is inserted. “Pronouncement of death can only be made after a sufficient time period has passed; as defined by hospital policy.”

2) Extracorporeal Membrane Oxygenation (ECMO).

ECMO is a technique that provides respiratory and cardiac support for patients whose lungs and heart are no longer working properly. In the case of a premature newborn infant the technique can be lifesaving, however in the case of ECMO during DCD, the procedure could have the effect of reviving a donor that is already dead. Its use has been described as designed “to resuscitate the donor after a formal declaration of cardiac death.”⁴ Therefore a person on ECMO is not actually dead but is considered so for the purpose of organ donation. The Model Elements which will now be binding Requirements include an implicit

³ <http://cbhd.org/content/donor-after-cardiac-death-what-christian%E2%80%99s-response>

⁴ Steven M. Rudich et al., *Extracorporeal Support of the Non-Heart-Beating Organ Donor (Letters to the Editor)*, 73 *TRANSPLANTATION* 158, 158 (2002).

endorsement of ECMO in DCD by requiring a protocol to be in place should a hospital utilize ECMO. Some involved in the organ transplant community object to the use of ECMO in an organ donor, however, the proposed requirements will make use of ECMO standard protocol.

- 3) The revisions include a requirement that patients with certain diseases who are conscious be considered for DCD.

The Model Elements donor criteria include patients with permanent and irreversible neurological injury. The Requirements now broaden this list to include patients with irreversible end-stage diseases of the respiratory and musculoskeletal systems (and the patient also could be conscious). There is concern that patients with an illness such as Lou Gehrig's disease might not be able to provide a true informed consent or might be pressured into foregoing life-sustaining treatment to prematurely donate their organs. DCD could present a severe moral hazard to the patient's decision to refuse life-supportive measures, creating an undue incentive to the decision.

- 4) The new Requirements delete the format currently in place assuring that a DCD candidate will not be evaluated as a potential donor prior to the hospital's primary healthcare team and the legal next-of-kin having decided to withdraw ventilated support or other life-sustaining treatment. In the revised Requirements a person/family/healthcare team that has not considered DCD could potentially receive an unsolicited evaluation in a sensitive situation.

- 5) We believe that the new Requirements might lead groups and hospitals involved in organ transplantation to violate the "Dead Donor Rule": "to hasten the death of a person whose death (through sickness or previous injury) is already inevitable is homicide in law; anyone removing organs from an apparently inanimate body (for instance, one retrieved from a serious traffic accident) must first ask himself whether he can positively pronounce the body dead."⁵

⁵ *Moment of Death*, BR. MED. J., Aug. 10, 1963, at 394. In more recent years, Youngner et al., declared the dead donor rule to be a fundamental moral requirement governing organ procurement and defined it that —vital organs should only be taken from dead patients, and correlatively, living patients must not be killed by organ retrieval. || Stuart I. Youngner et al., *Ethical, Psychosocial, and Public Policy Implications of Procuring Organs From Non-Heart-Beating Cadaver Donors*, 269 JAMA 2769, 2771 (1993).