



THE NATIONAL CATHOLIC BIOETHICS CENTER

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November 11, 2011

John R. Lake, MD
President, Board of Directors
Organ Procurement and Transplantation Network/United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23218

Dear Dr. Lake:

I am writing as President of The National Catholic Bioethics Center (NCBC) to provide comment to the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Board of Directors, and to encourage rejection of the *Proposal to Update and Clarify Language in the Controlled Donation after Circulatory Death (DCD) Model Elements*.¹ We understand that UNOS/OPTN is currently in the process of revising what since 2007 have been “Model Elements” (i.e., guidelines) to what will soon be binding “Requirements” for OPTN members. At a minimum, the call for comment should be reopened to allow for a full notice and period of comment for all who will be impacted by the changes to the requirements for participation.

The NCBC is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences, including biomedical research. The Center serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.

As you undoubtedly know, the Catholic Church encourages organ donation as providing the gift of life to those in need. Our Center has often reflected on and written about the moral challenges associated with organ donation. I personally participated in the National Conference on DCD that was held in Philadelphia in 2005 the proceedings of which were subsequently published in *The American Journal of Transplantation*. The NCBC welcomes the opportunity to address the OPTN/UNOS regarding this DCD proposal, and it is grateful that the OPTN is attempting to provide greater transparency to the procedures by inviting public commentary.

¹ Organ Procurement Organization (OPO) & Organ Availability (OAC) Committees, United Network for Organ Sharing, Proposal to Update and Clarify Language in the DCD Model Elements (2011), http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf [hereinafter PROPOSAL]. DCD refers to organ donation after cardiac death.

I will outline our concerns related to the Proposal:

Concerns for Provisions within the Proposal

It appears that The Proposal represents a shift to mandatory “Requirements” from “Model Elements and Guidelines”. It is our understanding that participating organizations in the past were expected to adhere to the “guidelines”. Does this proposal represent a significant change in past practices or is it basically a change in terminology? All transplant centers and Organ Procurement Organizations (OPO) must adhere to policies of UNOS, which is binding for participation in OPTN. If the UNOS disagrees with the policies of the OPO it will require the OPO to change them. This may have been the policy in the past; we do not know. The Proposal description states, in part:

These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies.... 1) OPOs and transplant centers must establish protocols that define the roles and responsibilities of the OPO and the transplant center for all activities associated with the DCD donor and 2) OPOs must have a written agreement with Medicare and Medicaid participating hospitals and critical access hospitals in its service area that describes the responsibilities of both the OPO and hospital concerning DCD.²

Furthermore, the Proposal, itself, contains new language, stated as follows:

1. Agreement:

The OPO must have a written agreement with hospitals that participate in DCD recovery. The participating hospital must be a Medicare and Medicaid participating hospital or a Critical Access Hospital as certified by Medicare. The participating hospital must also have a ventilator and a functional operating room.

2. Protocols:

OPOs and transplant centers shall establish protocols that define the roles and responsibilities of the OPO and transplant centers for the evaluation and management of potential donors, organ recovery and organ placement in compliance with OPTN policy.³

² “Organ Procurement Organization (OPO) and Organ Availability (OAC) Committees,” *At a Glance: Proposal to Update and Clarify Language in the DCD Model Elements*. See https://docs.google.com/viewer?url=http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf.

³ “Model Elements Requirements for Controlled Donation after Cardiac Circulatory Death Recovery (DCD) Protocols,” *At a Glance: Proposal to Update and Clarify Language in the DCD Model Elements*. See

The Proposal does state that the guidelines it contains should not be the only resource consulted when developing DCD protocols. However, there is the potential that hospitals that are to have a donor recovery agreement with the OPO, which now has to implement the new “Requirements” pursuant to participation with UNOS, may have a conflict of interest as the primary care-giver of the donor depending on what UNOS may require. Conflicts may arise concerning their convictions with respect to their adherence to the Dead Donor Rule⁴ and the standards advised by the Institute of Medicine regarding the obligations of the provider first to have secured the family’s decision to remove life-sustaining medical treatment before any dialogue occurs with the OPTN. This is particularly true since the proposal description describes the mandatory nature of the proposed “Requirements:”

DEQ [UNOS Department of Evaluation and Quality] staff will request a corrective action plan if the OPO or transplant center’s documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.⁵

In any event, the NCBC is aware of the Specific Requests for Comment to the following:

- Changing “cardiac” death to “circulatory” death;
- Withdrawal of “life sustaining measures” to “medical treatment/support”; and
- The addition of the term “disease” which is included in the suitable candidate evaluation section.

Changing “cardiac” death to “circulatory” death;

“Death due to permanent and irreversible loss of circulatory and respiratory function has been referred to as “donation after cardiac death” or DCD in current OPTN requirement language. The proposed revised language, “donation after circulatory death,” reflects current language used in the medical community to describe these criteria for death”. (Proposal.)

https://docs.google.com/viewer?url=http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf

⁴ Committee on Non-Heart-Beating Transplantation II-The Scientific and Ethical Basis for Practice and Protocols-Division of Health Care Services-Institute of Medicine: *Non-Heart-Beating Organ Transplantation: Practice and Protocols*. Edition 2000 edition. Edited by Medicine I. Washington, DC, National Academy Press; 2000:156.

⁵ “Monitoring and Evaluation,” *At a Glance: Proposal to Update and Clarify Language in the DCD Model Elements*. See

https://docs.google.com/viewer?url=http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_283.pdf

NCBC Comment:

The NCBC is aware of the critical commentary (Veatch and others) disputing irreversibility when the heart of the dead patient can resume circulation in another patient following transplantation. Thus, the NCBC understands the change in terminology from Donation after *Cardiac* Death to Donation after *Circulatory* Death ---as the UDDA defines death as an irreversible absence of *circulation*.

However, the proposal creates confusion regarding the determination of death:

Pronouncement of Death

“Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy”.

The proposal strikes the following sections that had been incorporated into the current “Model Elements”:

~~**How is irreversibility defined?**~~

~~**How is the permanent absence of circulation determined?**~~

NCBC comment:

The definition of death as referenced to the Uniform Determination of Death Act (UDDA) states the following: "An individual who has sustained either irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem is dead”.

The proposal strikes the removal of the period of observation to determine that the absence of circulation and respiration is **irreversible**. The importance of that period is to witness asystole by the physician and healthcare team responsible for end-of-life care of the patient.

The waiting period to rule out spontaneous resumption of circulation could become entirely arbitrary with someone being declared dead in one hospital and being alive in another. The Institute of Medicine recommendation is 5 minutes,⁶ but this Proposal leaves it up to the individual hospital --with no national guidelines established. This is a matter of considerable concern.

The NCBC also understands the concept of permanence as it applies to irreversibility--- that is, the absence of circulation is irreversible if it is permanent. Under “Sources” of the

⁶ Committee on Non-Heart-Beating Transplantation II-The Scientific and Ethical Basis for Practice and Protocols-Division of Health Care Services-Institute of Medicine.

current “Model Elements”, the *American Journal of Transplantation* (February 2006) was referenced which defined “irreversibility” by the Report of the National Conference on Donation after Cardiac Death that cited objective tests that could be performed to determine permanent cessation of circulation. The requirement of these tests has been stricken in their entirety from the proposed new policy, and it is now stated that each hospital will establish its own protocols. The confusion anticipated by an absence of guidelines as developed by the National Conference should be carefully considered by those making this proposal. **The NCBC objects to the striking of these sections without replacing the sections with appropriate guidelines.**

Moreover, the term “permanent” is now applied to neurologic injury as shown in **C. Candidate Evaluation**. Permanence has been applied previously only to the irreversible absence of circulation.

*C. Candidate Evaluation.....A potential DCD donor should then be evaluated by the primary healthcare team and the local OPO to determine if the candidate meets the following criteria: A patient, from age newborn to the Donation Service Area’s (DSA) defined upper age limit, with a **permanent** and irreversible neurological injury (i.e. upper spinal cord injury), or permanent and irreversible disease (i.e. end-stage musculoskeletal or pulmonary disease) that results in necessary life-sustaining medical treatment or ventilated support but who does not fulfill the neurologic criteria for death, may be a suitable candidate for DCD.*

NCBC Comment:

The proposal gives no explanation as to how permanent neurologic injury is determined.

The NCBC recognizes that this section has to do with suitability of organ recovery but strongly recommends a more clarified explanation as to not be confusing regarding the determination of death:

“The Model Elements currently require an assessment to determine whether death is likely to occur (after withdrawal of life sustaining medical treatment/support) within a timeframe necessary for organ donation. This language was deleted because there is no industry standard that allows for a true assessment of the likelihood of death within a specific time frame. Each hospital establishes its own timeframe for organ acceptability”.

Removing the requirement that family and primary health care provider must first determine that it is appropriate to withdraw life-sustaining treatment creates a potential conflict of interest for the primary care physician. It is proposed that even before this decision has been made by the family to withdraw life-sustaining medical treatment/support, the local OPO and the primary health team are to make a determination if donor candidate criteria have been met. Thus, a person with chronic obstructive pulmonary disease, who is on a ventilator and even awake, can be considered by his provider and the local OPO as a donor candidate, and *then* be approached with the possibility of sedation and removal of ventilation for the purpose of being a donor. Furthermore, in 2000, the Institute of Medicine explicitly recommended that “the decision to withdraw life-sustaining treatment should be made independently of and *prior to* any staff-initiated discussion of organ and tissues donation.”⁷ This commitment was reaffirmed by the IOM in its 2006 report.⁸

The broadening of donor candidate criteria is dangerously expansive. Donor criteria which include patients with permanent and irreversible neurological injury (current language) have been broadened to include patients with irreversible end-stage diseases of the respiratory and musculoskeletal systems (and the patient also could be conscious). Thus, a patient with an upper spinal cord injury, or emphysema, or amyotrophic lateral sclerosis, on a ventilator and alert, and who also may be depressed, could be sedated, removed from the ventilator, declared dead in a non-specified period and become an organ donor. In fact, the Proposal indicates that a person with an upper spinal cord injury who is on ventilator or other life-sustaining medical treatment does not have to be end-stage to be considered as a donor. There is no recognition of the fact that depression plays a key role in the wish to terminate one’s life; and depressed persons,⁹ especially those with disabilities (and perhaps even through their exhausted family caregivers), can be discriminated against as they erroneously are presented with options that may provide what is perceived to be an “heroic end.”

The very categories of persons identified as potential donors are persons with significant disabilities of spinal cord injury or respiratory and neuromuscular disease, who should not be presented with premature options as if their lives are not as valued as those without disabilities.

Changing terminology of withdrawal of “life sustaining measures” to “life sustaining medical treatment/support” raises other ethical issues. This proposed

⁷ Committee On Non-Heart Beating Transplantation Ii, Institute Of Medicine, Non-Heart-Beating Organ Transplantation: Practice And Protocols 16 (National Academy Press 2000) (emphasis added).

⁸ Committee on Increasing Rates of Organ Donation, Institute of Medicine, Organ Donation: Opportunities for Action 136 (James F. Childress & Catharyn T. Liverman eds., National Academies Press 2006).

⁹ A study published in the *British Medical Journal* followed 58 patients in Oregon who requested aid in dying. Most were terminally ill with cancer or Lou Gehrig’s disease. Of the 58, twenty-six percent were independently diagnosed with depression. See: [Linda Ganzini](#), [Elizabeth R Goy](#), [Steven K Dobscha](#), “Prevalence of depression and anxiety in patients requesting physicians’ aid in dying: cross sectional survey,” *British Medical Journal* (2 August 2008), Abstract.

provision would seem to permit the withdrawal of such basic care as medications and assisted nutrition and hydration especially in a non-end stage patient with an upper spinal cord injury resulting “in necessary life-sustaining medical treatment or ventilated support.”

Missing in the proposal is the concept of futility in the withdrawal of medical treatment/support and the elaboration of consent for the withdrawal of extraordinary measures of treatment. Unless those criteria are fulfilled the removal of life-sustaining medical treatment support may be unethical.

Changing terminology of “Cardiac Death” to “Circulatory Death” is not an issue if the protocol precludes the use of the extracorporeal membrane oxygenation (ECMO), which bypasses the heart and lungs while artificially perfusing all body organs of the non-heart beating donors. Its use in such cases has been described as designed “to resuscitate the donor after a formal declaration of cardiac death.”¹⁰ The ECMO is oxygenating all organs, including the brain. But a person who is not dead but on ECMO support could theoretically be erroneously considered dead for the purpose of organ donation. This is facilitated by the Proposal deleting criteria for determining the permanent absence of circulation. Furthermore the protocol should preclude the use of EISOR (extracorporeal interval support for organ retrieval), which involves placing an occlusion balloon in the thoracic aorta to prevent the oxygenated blood from reaching the heart and the brain, thus avoiding reanimation,¹¹ effectively *causing* brain death.

Statement of Request:

It is essential that any programmatic change in a governmental program occurs with ample opportunity for providers, potential donors, and the public to have adequate notice and a sufficient period of comment on the substantial changes from the current model elements to mandated requirements for participation. We appreciate being given the opportunity to comment on these proposed changes. However, we believe the short notice given for comment was inadequate for the populations served by UNOS.

The Proposal appears to be changing a model elements policy into a requirement for participation with an inadequate method of securing public comment. UNOS documents indicate that when an Organ Procurement and Transplantation Network (OPTN) Committee proposal is to come before the OPTN/UNOS Board of Directors, UNOS publishes the proposal “for public comment by other committees, OPTN/UNOS regions and interested persons or organizations.”¹² UNOS documents indicate that the publication process at the drafting stage consists of presentation on the OPTN website and an opt-in e-

¹⁰Steven M. Rudich et al., “Extracorporeal Support of the Non-Heart-Beating Organ Donor (Letters to the Editor),” *TRANSPLANTATION* 73:158 (2002), 158.

¹¹Mark T. Gravel, et al., “Kidney Transplantation from Organ Donors Following Cardiopulmonary Death Using Extracorporeal Membrane Oxygenation Support,” *ANNALS OF TRANSPLANTATION* 9:57, 57-58. See also Carla DeJohn & Joseph B. Zwischenberger, “Ethical Implications of Extracorporeal Interval Support for Organ Retrieval (EISOR),” *ASAIO JOURNAL* 52:119 (2006), 119-122.

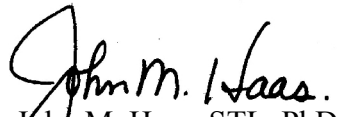
¹²United Network for Organ Sharing, UNOS and the OPTN: Getting Involved in the Public Comment Process (2011), http://optn.transplant.hrsa.gov/ContentDocuments/PublicComment_FactSheet.pdf.

mail notification system.¹³ It is only after the final Board decision concerning the policy proposal has been made that OPTN/UNOS directly and proactively communicates to the OPTN/UNOS members, with a Policy Notice.¹⁴ Such a process is hardly seems consistent with other federal regulatory proposals, particularly when a model elements policy is being converted into a mandatory requirement for participation. At a minimum, we request that the comment period be reopened, with sufficient notice to the aforementioned populations, so that there is greater transparency in the way in which their government-funded program is implemented.

The NCBC respectfully requests a response to the issues that have been elaborated so that it can share a supportive perspective regarding these proposed policy changes with the healthcare institutions in United States and throughout the world that will be influenced by this policy. Thank you for all that the OPTN/UNOS does in the service of life, and the NCBC appreciates the opportunity to provide this commentary.

Thank you for all your organizations do in the service of life, and we thank you for giving us the opportunity to comment.

Sincerely yours,



John M. Haas, STL, PhD.
President

¹³ *Id.*

¹⁴ *Id.*