Title: NRP and US Legal Standards for Determining Death Are Not Aligned

Authors: Alexandra K Glazier, JD MPH*
New England Donor Services
60 First Ave
Waltham, MA 02451

Alexander M Capron, LLB MA(Hon)
Gould School of Law & Keck School of Medicine
University of Southern California
699 Exposition Blvd
Los Angeles, CA, USA 90089-0071

Corresponding author*: Alexandra K Glazier
New England Donor Services
60 First Ave
Waltham, MA 02451
aglazier@neds.org
617-529-3396

Abbreviations: donation after circulatory determination of death (DCDD)

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/AJT.17002

This article is protected by copyright. All rights reserved
Normothermic Regional Perfusion (NRP)
extracorporeal membrane oxygenation (ECMO)
Uniform Determination of Death Act (UDDA)

Word Count: 901
The U.S. Department of Health and Human Services is currently using regulations and collaborative projects to encourage organ procurement organizations to obtain more organs from donation after circulatory determination of death (DCDD). One barrier to transplant programs using such organs has been the concern that loss of circulation in DCDD renders the organs less desirable for transplantation. Programs in other countries have responded by developing a protocol—Normothermic Regional Perfusion (NRP)—to improve the quality and quantity of transplantable organs. Under NRP protocols, after death has been declared, circulation is restored by a means such as extracorporeal membrane oxygenation (ECMO), while steps such as intravascular balloons or ligation of arteries are also taken to concentrate support on the organs to be transplanted and to avoid circulation reaching the brain.

Although proponents of such protocols have urged adoption in the U.S., last April the American College of Physicians issued a critical assessment of the ethics of NRP—which it termed “a protocol more accurately described as organ retrieval after cardiopulmonary arrest and the induction of brain death”—and urged a pause to allow further study before wide adoption. In this issue of the Journal, Parent et al. and Wall et al. take issue with that assessment and argue that NRP protocols are ethically acceptable. Unfortunately, both groups rely at several points on the concept of “intent,” which is absent from the legal standards for death determination. Their arguments thus fail to address concerns that must be resolved to ensure NRP protocols are in compliance with existing law.

All states follow the legal standards established by the Uniform Determination of Death Act (UDDA). Under these laws, an individual has died when either circulation or all functions of the entire brain function have ceased irreversibly. For years the term “irreversible” (cannot be changed) has been interpreted as “permanent” (will not change). Accordingly, an individual is dead under U.S. law when circulation has ceased and will not return through either auto-resuscitation or medical intervention.

Parent et al argue that under NRP protocols, death is declared “in strict accordance with death declaration requirements,” and Wall et al point out that the declaration protocol for NRP is the same as in standard DCDD cases. With NRP, however, after death is declared, circulation resumes with artificial support. This is consequential legally because it contradicts the legal requirement that death depends on circulation having permanently ceased.
Parent et al. try to escape this conclusion by claiming that a loss of circulation can nonetheless be classified as “permanent” when the medical team has accepted a patient’s instruction not to make any efforts at resuscitation. The authors assert that when circulation is restored “there is no intention or attempt to resuscitate because doing so would be medically ineffective.” Whatever the intention, the fact remains that NRP restores circulation and, indeed, can restore heartbeat. Wall et al. make a similar argument but switch the intention from the physician to the patient. They claim that since NRP aims only to maintain the viability of donor organs prior to retrieval, it is therefore “an act of organ preservation, which the donor or surrogate intended.”

Although intentions may be important when evaluating the ethical acceptability of physicians’ actions, the legal standard for determining death is bare of intent: a patient is dead when circulation neither can nor will resume. That the patient is in a state where meaningful existence is not possible, that trying to induce spontaneous resumption of circulation would be futile, or even that the NRP protocol is consistent with the donor’s wishes, are all irrelevant to whether the patient is deceased under U.S. law, which turns on the person’s physical condition not on anyone’s intention.

Further, when physicians occlude the carotids in NRP they may indeed intend to improve organ viability but it is also true that preventing oxygen from reaching the brain removes the risk that in some DCDD patients the restoration of bloodflow to the brain could prompt at least temporary resumption of functions that are inconsistent with either or both the neurological or the circulatory-respiratory standard for determining death. An ambitious district attorney might convincingly argue that physicians following the NRP protocol also intended to render irreversible any brain functions that had not permanently ceased, thus ensuring the patient’s death.

Several ways out of this legal conundrum are possible. First, using perfusate rather than oxygenated blood may mean that what is being done in NRP does not constitute a resumption of “circulation.” Alternatively, some state attorneys general might be willing to issue a legal opinion that the NRP protocol complies with the UDDA; though unlikely, this option would remove concerns about legal liability. Or, after ventilator withdrawal and asystole, if death were diagnosed based on the loss of brain functions, then contradicting the circulatory standard would not be legally relevant. However, the time needed for a neurologically based determination of death in a body without heartbeat may impair organ viability. Fourth, the Uniform Law Commissioners are considering
revising the UDDA, which presents an opportunity to address the misalignment between law and emerging practices such as NRP, though any legal “redefinition” of death done solely to benefit transplantation could undermine public trust in death determinations, with adverse consequences for deceased donation. Finally, transplant scientists could further develop methods of ex vivo support for organs, thereby obviating the need for in vivo circulation that negates the legal basis for declaring death.³

REFERENCES
1. 42 CFR Part 486.