

**OPTN Ethics Committee
Normothermic Regional Perfusion (NRP) Workgroup
Meeting Summary
August 11, 2022
Conference Call**

Keren Ladin, PhD, Chair

Introduction

The Normothermic Regional Perfusion (NRP) Workgroup met via Citrix GoToMeeting teleconference on 08/11/2022 to discuss the following agenda items:

1. Presentation on Ethical Implications of NRP
2. Recap of 8/2/2022 Meeting
3. Uncontrolled DCD Scenario - Discussion

The following is a summary of the Committee's discussions.

1. Presentation on Ethical Implications of NRP

Alex Glazier, JD, MPH, presented on aligning law, ethics, and practice in declaring death and donation protocols. The presenter highlighted the legal requirements as the bottom line that needs to be met and the ethical standards that ought to be considered once that legal threshold has been met.

Summary of discussion:

A member inquired if intent matters, in terms of resuscitating the heart in order to better preserve the organ for donation. The presenter responded that the law excludes intent and it may be relevant for an ethical analysis but it is not included in a legal analysis. The presenter did note that there may be a distinction between resuscitating the organ versus resuscitating the donor. In response, a member opined that the circulation that occurs in NRP is after the declaration of death, which is permanent, and happens in a closed circuit without flow to the brain. The member suggested that circulation has more to do with personhood and ability to interact. The presenter responded that would be pertinent and echoes the need for a more unified concept of death. Since the patient is not deceased by cardiac death criteria it is possible that the criteria for brain death may not be met at this time and suggested that empirical data would be helpful for these discussions.

A member inquired about the waiting time for auto resuscitation as not being clinically relevant and the greater question is whether brain death has occurred. The presenter agreed that while the two-minute waiting period for standard DCD is designed to cover the autoresuscitation potential but it does not provide a sufficient time frame for brain death to occur. The member noted that in Italy, procurement teams wait 20 minutes after death by cardiac criteria to proceed with organ donation to ensure that brain death has occurred.

A member inquired about the use of a two to five-minute waiting period and if a seven to ten-minute waiting period would be a preferred time-out period for NRP. The presenter noted that two minutes is the protocol for standard DCD and that a seven to ten-minute time out period could be a best practice or recommendation if supported by empirical studies. A member who participates in NRP shared that their center has a five-minute waiting period and is not familiar with OPOs or transplant centers that use

a waiting period of less than five minutes. When considering if the suggestion of a seven to ten-minute waiting period is meaningful, the law defers to medical expertise in this area.

A member inquired about what statutory change to the Uniform Determination of Death Act (UDDA) would need to occur to pursue NRP. The presenter emphasized the need for a unified concept of death first and foremost. If that could be achieved, then there could be potential to revise the language to agree with NRP. The presenter noted that the inclusion of 'spontaneous' and revise irreversible to 'permanent' would help align the legal threshold for death with the practice of NRP but not fully resolve the issues at hand. The presenter cautioned against gerrymandering the law to support what medical professionals want to occur. Ultimately, it is important to remember that the ethical analysis of NRP is happening within the current legal framework.

2. Recap of 8/4 Meeting

The Chair provided a recap of the last meeting, where the University of Minnesota (UMN) presented their process for considering the ethical implications and deciding to pursue NRP. Last week's discussion emphasized now wanting to burden donor families with too much information during the consent process. The donor family member shared their experience and perspective, noting that the declaration of death cannot occur twice because it would undermine the declaration of death by cardiac criteria (DCD) and identified NRP as a distinct and separate action from the declaration of death. The member emphasized the importance of honoring the donor's, or surrogates', autonomy in deciding to proceed with organ donation. The member added that intent is important. The member noted the importance of explaining the interventions and treatments used prior to death to provide consent but noted the level of interest donor families would have in the details of organ procurement because their loved one is already deceased. The member highlighted the state of mind of families at the time and suggested providing more support and services to families after the donation as they grieve and process their decision. The member concluded that trust in the system and process was of the utmost importance when donor families are in such a vulnerable state.

Summary of discussion:

Members were grateful to hear the feedback from the donor family perspective which illuminated the group's philosophical concerns in a practical way. The Chair highlighted the importance of providing care that corresponds with the decisions made by the patient to be a donor while ensuring a high standard of consent and care are provided. The Chair echoed the importance of the relationship and trust in the relationship between donor families and their loved ones care team. A member added that the American Society of Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) is developing a joint guidance document for donor family communication in NRP cases with the hopes of promoting transparency, respect, and stewardship in line with the sentiment shared today.

3. Uncontrolled DCD Scenario - Discussion

The Chair presented the scenario of uncontrolled DCD where a patient arrives in the emergency room and ultimately dies by cardiac criteria after every attempt was made to save their life. In this instance, the donor and their family are unable to have a discussion about NRP and factor it into their decision to proceed with organ donation. The Chair asked the group to consider that if this scenario should be treated the same as other NRP cases or if the inability to discuss NRP with the donor family requires additional consideration.

Summary of discussion:

A member elaborated on this situation, which primarily occurs in Spain, that all resuscitation attempts are made before the patient is declared dead, as opposed to withdrawing life support and providing

end-of-life care. In these settings, first-person authorization for donor designation is acceptable to proceed with organ donation. A member inquired how the evaluation and logistical process for determining donation exist in practice. The member inquired at what point during resuscitation attempts, attempted communication with the family, determining organ donor designation, etc. does the process transition to organ procurement and NRP within the uncontrolled DCD emergency room setting. The member responded that currently, this practice is not being used in the U.S. so these are really important questions that need answers but do not have them readily available. Theoretically, the clinical team would move forward with first-person authorization as granted on the registration list and make efforts to contact next of kin for support and authorization. Currently, this practice is done in Europe so this scenario is more theoretical for this group.

A member highlighted the current challenge with proceeding with uncontrolled DCD and how these concerns are parallel. The Chair shared that she has received calls from hospitals that are engaging in uncontrolled NRP which has caused moral distress and concern and highlighted the need for the group to think about the practical implications of this.

Next steps:

The group will be separating into subgroups to address the ethical implications in greater detail. Members will receive communication from UNOS staff to sign up for subgroups and schedule those meetings.

Upcoming Meetings

- August 25, 2022
- September 8, 2022

Attendance

- **Committee Members**
 - Andy Flescher
 - Carrie Thiessen
 - Erin Halpin
 - Glenn Cohen
 - Jonathan Fisher
 - Julie Spear
 - Keren Ladin
 - Kevin Myer
 - Lainie Ross
 - Sanjay Kulkarni
 - Sena Wilson-Sheehan
 - Sophoclis Alexopolus
- **HRSA Representatives**
 - Edna Dumas
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Kaitlin Swanner
 - Kim Uccellini
 - Krissy Laurie
 - Laura Schmitt
 - Matt Belton
 - Susie Sprinson
 - Stryker-Ann Vosteen
- **Other Attendees**
 - Alex Glazier
 - Joel Wu