OPTN Ethics Committee
NRP Workgroup – Intent and Time Out Subgroup
Meeting Summary
September 15, 2022
Conference Call

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Introduction

The Normothermic Regional Perfusion (NRP) Workgroup – Intent and Time Out Subgroup met via Microsoft Teams teleconference on 09/15/2022 to discuss the following agenda items:

1. Welcome and Agenda Review
2. Discussion of relevant literature, potential outline, assignments, and key questions
3. Next steps and closing remarks

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

1. Welcome and Agenda Review

UNOS staff introduced the subgroup and briefly reviewed their task of considering the intent of NRP and the time out period between death declaration and the initiation of NRP procurement. These considerations will be compounded with the 'irreversibility' subgroup to comprehensively address the topic of the legitimacy of death designation.

2. Discussion of relevant literature, potential outline, assignments, and key questions

Summary of discussion:

Intent

The committee discussed how surgeons do things that are inherently harmful, such as cutting a patient, but that these harms are justified by the larger intent of helping the patient. A member proposed that NRP can be framed in this way as well. To what extent does intent matter for NRP?

The subgroup considered the intent of the donor or donor family and how it factors in to NRP. The subgroup agreed that the intent of the donor and surgical team must be in alignment, and that alignment is necessary but may not be sufficient to ethically justify NRP. Discussion transitioned to how consent and intent of NRP allows surgeons to perform local regional perfusion, but not resuscitate the person.

The lead asked a hypothetical: if surgeons were to perfuse the entire body and then ligate the vessels to achieve regional perfusion, does this change the morality? Members agreed that this would change the morality and may violate the "do no harm" principle. A member explained that this question is contingent on whether there is the potential for meaningful brain activity after five minutes, data that does not exist yet.

A member pointed out that the do no harm principle only applies to living people, and discussed how in NRP, using the do no harm principle is potentially confusing because the person has already been declared dead. The members discussed the role of morphine or other pain medications in the donation process as related to NRP, and how comfort measures are routine in withdrawal of life support. The

committee considered specifics of withdrawal of life support to explore the role of morphine and propofol.

Determination of death

A member asked if NRP changes determination of death by moving from circulatory death to brain death. The committee discussed how from a surgeon's perspective, once someone is declared dead, it is not possible to be alive again. A member explained that in NRP, the donor has already expressed intent to donate organs, and even if they may auto resuscitate, they did not want that. A member brought up how from the family's point of view, the patient has died well before NRP begins in accordance with their intent.

The committee focused on if a person is dead after the first declaration of death regardless of intent and considered a case where someone is resuscitated multiple times. A member described a theoretical case of someone who was under-resuscitated is not "brought back from the dead." The subgroup clarified the definition of autoresuscitation as recovery of spontaneous beating of the heart and explained that there is a five-minute hands-off period to ensure that autoresuscitation does not occur. There was some debate about the validity and reasonability of the five-minute hands-off period. Literature supports the five-minutes, but questions may remain about the ethical and philosophical reasonability and practicality of that time period.

The subgroup discussed that during NRP, clamping arteries to the brain to prevent the possibility of resuscitation allows brain death to proceed as the donor intended. The committee focused on if NRP simply allows brain death to occur at the natural pace, or if it impacts the process by preventing blood flow. There was some disagreement on this point, and a member asked if there is an ethical difference to reperfusion in situ vs ex situ.

The members considered thoracoabdominal (TA)-NRP vs abdominal (A)-NRP. They explored how by restarting the heart in NRP is not reanimating a person, but because death was declared by circulatory criteria, when you restart the heart, you lose the designation of death that was previously relied upon. A member explained that ligation serves to ensure brain death and may switch the designation criteria in the process. Another member disagreed with this reliance on definitions, and instead advocated for using perfusion to the brain and brain activity as the focus of the question.

A member described that the reason there is so much discomfort in using NRP is that the process is not totally aligned with US laws about declaration of death, and that changing laws is outside the scope of both medical ethics and the role of physicians. Members discussed that it might be best to outline the arguments and ethical concerns in the white paper instead of attempting to reconcile perspectives. A member brought up possible connections to imminent death donation. There is a spectrum of justification for NRP, reliant on differing values and ethical perspectives.

3. Next steps and closing remarks

Members will review relevant literature before the next meeting. UNOS staff will circulate questions that came up during this meeting to allow members and other stakeholders to prepare comments.

Upcoming Meetings

- September 22, 2022 – Full NRP Workgroup Meeting
- Next subgroup meeting to be determined

Attendance

- **Subgroup Members**
  - Carrie Thiessen
  - I.Glenn Cohen
  - Jonathan Fisher
  - Keren Ladin
  - Nader Moazami
- **HRSA Representatives**
  - Jim Bowman
- **UNOS Staff**
  - Cole Fox
  - Laura Schmitt