

**OPTN Ethics Committee
NRP Workgroup – Irreversibility Subgroup
Meeting Summary
September 12, 2022
Conference Call**

Andy Flescher, PhD, Lead

Introduction

The NRP Workgroup –Irreversibility Subgroup met via Microsoft Teams teleconference on 09/13/2022 to discuss the following agenda items:

1. Welcome and Agenda Review
2. Subgroup expectations and proposed assignments
3. Discussion of key questions

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 with respect to NRP, the irreversibility of death and death declaration. These considerations will be compounded with the ‘intent and time out’ subgroup to comprehensively address the topic of the legitimacy of death designation.

2. Subgroup expectations and proposed assignments

Summary of discussion:

The vice-chair outlined proposed assignments of members at a high level.

3. Discussion of key questions

Summary of discussion:

- What are the implications of irreversibility vs permanence on NRP?

A member raised a question of if the distinction between irreversibility and permanence really matters, so long as a patient is declared dead. Another member answered that it matters because the distinction between causing (active) the permanence or simply allowing the permanence to occur (passive) is ethically relevant. The vice chair responded, saying that it is important to acknowledge the distinction between irreversibility and permanence, but that it is not directly relevant to the task of this subcommittee to go further than that. A member responded by stating that the goal of the committee should be to acknowledge that there may be a difference and outline the contentious points, but not necessarily to come to a conclusion. The vice chair stated that it is important to go beyond simply a utility viewpoint, and if the committee produces a paper, this should be clearly stated.

- Is there a difference between utilitarian and moral concerns, and what is the relevance of both to this committee?

The subcommittee transitioned to discussing if there is a distinction between utilitarian concerns and moral concerns such as the dead donor rule. A member raised that this is a question of utilitarianism vs

deontology. A member referenced an earlier call with European colleagues discussing NRP and noted that they did not seem to share the same direct concerns about patient autonomy and consent. The vice chair responded that while all these questions are relevant to NRP, they are not directly tied to the task of this subcommittee, which is to describe irreversibility vs permanence in the context of NRP.

- What are the considerations of autonomy and withdrawal of care in NRP?

A member discussed how there may be a lack of pushback in other countries doing NRP because of a lower standard of transparency, but that to maintain autonomy and respect for persons, the difference between reanimation, recirculation, and resuscitation will need to be carefully explained in the US. The member pointed out that without the intent to donate organs and NRP, restarting a heart using ECMO would be called resuscitation. Another member discussed the importance of determining if there is an ethically significant difference between unaided circulation vs. assisted circulation, and if this will impact the discussion of reversibility and permanence. A member asserted that there is not an ethically significant difference, because a patient on ECMO with COVID or acute respiratory distress syndrome is alive, but it is difficult to understand the distinction between this example and NRP, as in both cases circulation is reestablished. The discussion then transitioned to the relationship between circulation and brain activity.

- Is blood flow to the brain necessary to be considered alive?

A member stated that blood flow to the brain is not necessary to be considered alive, but another member countered by saying that if that is the case, the distinction between donation after circulatory death (DCD) and donation after brain death (DBD) could be in jeopardy. The original member brought up a recently published editorial opining that if NRP converts a DCD to a DBD donor, “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.”¹ A member questioned if that could be possible after declaration of death. The vice chair asserted that a definitive answer to this question will be hard to agree upon. A member raised the concern that brain death does not occur at the same time cardiac death occurs. Another member clarified that in DCD, brain death is declared five minutes after cardiac death. The original member asserted that the five-minute waiting period is to ensure the impossibility of autoresuscitation, not to ensure brain death. That member offered that in NRP, the clamping of the blood vessels could be ensuring death, because without that blood flow to the brain could be reestablished. Another member stated that intent matters, because all NRP donors already intended to donate organs. This member transitioned to talking about what the committee needs in order to provide the public with transparent and thorough explanations about what NRP entails. The vice chair identified the importance of providing the public with resources to ensure NRP's transparency.

A member brought up that more data is needed regarding how long brain death occurs after cardiac death. A member discussed if the committee will need to reargue DCD to allow for NRP, and another member pushed back, stating that DCD is not up for debate, only the hands-off period. Another member discussed how in donation, all organs are technically reanimated, and that there may not be an ethically significant difference between perfusing an organ in situ vs ex situ. The member explained that in DCD, the actions taken (such as clamping the aorta) are the same as in NRP.

¹ Glazier, A.K. and Capron, A.M. (2022), Normothermic regional perfusion and US legal standards for determining death are not aligned. *Am J Transplant*, 22: 1289-1290. <https://doi.org/10.1111/ajt.17002>

- Is permanence irreversible?

The vice chair brought up that because we have faith in the first declaration of death, permanence is irreversible. There was some confusion among members on this point. A member tried to clarify by explaining that in resuscitation of a patient outside of a donation context, that patient was not considered medically or legally dead unless resuscitation fails. However, in donation, declaration of death occurs first. A member then posed a hypothetical: consider a case of NRP where the clamp preventing perfusion to the brain fails. What are the implications for death?

- What is the role of the clamp preventing perfusion to the brain? What is the answer to the above hypothetical?

A member questioned the precision of a five-minute hands-off waiting period. The vice chair explained that it might be best to simply raise these questions and provide the community with information and data to consider. The subcommittee went back to discussing the hands-off period, and how that may impact the brain, death irreversibility, and NRP. The vice chair asserted that there are many questions to be considered.

Next steps:

The vice chair offered to lay out the distinctions in death between causing (active) the permanence or simply allowing the permanence to occur (passive) and lay groundwork for why NRP is passive. He poses that other members will work on the other questions discussed in the meeting, various other accounts of what is happening in NRP, to include irreversibility and permanence, the hands-off period, and potential legal issues at a minimum. Another group will be meeting about intent and time-out on September 15th.

Upcoming Meetings

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

Attendance

- **Subgroup Members**
 - Andy Flescher
 - Carrie Thiessen
 - Jonathan Fisher
 - Lainie Ross
 - Matt Hartwig
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Representative**
 - Bryn Thompson
- **UNOS Staff**
 - Cole Fox
 - Kim Uccellini
 - Krissy Laurie
 - Laura Schmitt
 - Roger Brown
 - Stryker-Ann Vosteen