

OPTN Ethics Committee
NRP Workgroup – Patient Autonomy, Consent, and Public Support Subgroup
Meeting Summary
September 13, 2022
Conference Call

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Introduction

The Normothermic Regional Perfusion (NRP) Workgroup – Patient Autonomy, Consent, and Public Support 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 the role of patient autonomy, informed consent, and public trust within NRP. These considerations will be developed by the subgroup to comprehensively address each important focus of the white paper.

2. Subgroup expectations and proposed assignments

Summary of discussion:

UNOS staff and a member outlined the expectations and norms for this discussion. Members introduced themselves and their background, including experience with NRP.

Next steps:

The goal of the subgroup is to map out the content that will appear in the white paper by mid-October.

3. Discussion of key questions

Summary of discussion:

The subgroup spent the meeting listing pertinent concerns to guide present and future discussions. These included:

Withdrawal of life support and consent to organ donation

A member brought up the separation of the decision to withdraw life support from consent for organ donation in the context of NRP, including the role of hospital trained requestors or designees. A member explained that typically, the term “designated requestor” covers all the models of OPO setup.

A member inquired, “what’s next” for a patient whose family has decided to withdraw life support relating to NRP. Is there a distinction between the conversation to withdraw life support and the conversation to donate via NRP? A different member asked how clinicians or hospital staff should go about difficult conversations with family in this instance, especially in time-sensitive cases?

Information provided to donors and donor families

A member asked how specific the details about the procurement procedure should be, as well as details involved in obtaining consent for ante mortem procedures like administration of heparin and cannulation. A member added that they are in favor of looking at the standard of what patients are told in coronary bypass surgery. Another member clarified that from a donor family perspective, the interest in details of recovery waned, because the member's loved one had already been declared dead. This member also cautioned about the vulnerability of families in crisis, and how susceptibility to misunderstanding is high. The member added that there may be room for follow-up after donation has occurred to better support donor families.

Consent specific to NRP

The member went on to elaborate concerns about the decision-making agent: how does the distinction between first person registered donors and third-party surrogate decision makers relate to NRP? How does this pertain to consent for the ante mortem procedures? A member inquired about if the wishes of the first-person registered donor and the surrogate decision maker conflict, such as if the patient consented to donation but a family did not consent to the ante mortem procedures involved in NRP?

A member explained that previously, NRP may have been considered Donation after Circulatory Death (DCD) research and asked if this was ever made clear on a registry status. This may depend on the registry.

A member questioned the ethical implications of being on the registry as presumed consent for NRP. Another member explained that in most cases, being on the registry is presumed consent to NRP, such as in Arizona. The committee then discussed if informed consent called into question when a family/patient previously consented to DCD but did not realize NRP was included. What are the implications of this on public trust in donation? The same concerns about public trust and donor consent are relevant to this discussion.

Donor wishes vs donor decisions

A member cautioned the use of the term "donor wishes" and explained that instead, the term "donor decisions" is more accurate. The term "decision" clarifies consent to families more easily and the committee expressed a desire for more research and surveys to donor families to guide decision-making.

Consent for recirculation

The subgroup described a concern regarding consent for recirculation of the heart and explained that consent is not a one-size-fits-all in this case. Consent for recirculation in situ and ex situ are not necessarily the same. A member explained that this could have significant implications for allocation, because not all heart programs will accept both, or either, type of recirculation.

Consent of recipients

The committee also considered the potential for an ethical burden to obtain consent or provide information to recipients that the organ they received was obtained through NRP. The members discussed how recipients are customarily told that the organ is from a DCD donor but some did not believe that consent was needed and regulatory guidance on the topic is vague. The subgroup explored the purpose of disclosure to a transplant recipient and noted that there are different risks associated with recovery types across organs. Details of procurement are usually shared with recipient candidates to discuss risks and benefits, and this would presumably be the same for NRP disclosures.

Next steps:

Members will review the slides and read the relevant literature linked in the slides before the next meeting.

Upcoming Meetings

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

Attendance

- **Subgroup Members**
 - Amy Friedman
 - Julie Spear
 - Kevin Myer
 - Lainie Ross
 - Sena Wilson-Sheehan
- **HRSA Representatives**
 - Jim Bowman
- **UNOS Staff**
 - Cole Fox
 - Laura Schmitt
 - Rebecca Murdock
 - Stryker-Ann Vosteen