

OPTN Ethics Committee

Meeting Summary

October 10, 2023

Detroit, MI

Andrew Flescher, PhD, Chair

Sanjay Kulkarni, MD, PhD, Vice-Chair

Introduction

The Ethics Committee met in Detroit, MI on 10/10/2023 to discuss the following agenda items:

1. Welcome
2. Normothermic Regional Perfusion (NRP) White Paper: Overview of Today's Goals
3. Follow-up from 10/5 Meeting
4. NRP Public Comment (PC) Feedback Review and Discuss Possible Post-PC Changes
5. Review and Consider Edits to NRP White Paper
6. New Projects
7. Closing Remarks

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

1. Welcome

The Chair, Vice Chair, and staff welcomed members to the meeting and introduced the agenda. Members participated in an icebreaker.

2. Normothermic Regional Perfusion (NRP) White Paper: Overview of Today's Goals

The Chair introduced the goals and plan for discussion regarding the NRP white paper.

Presentation Summary:

The Chair introduced the goals and plan for the discussion regarding the NRP white paper:

1. Review the public comment feedback not covered during the 10/5 meeting
2. Discuss and consider potential post-PC changes by section
3. Review and discuss the document itself with the full Committee
4. Review minor/non-substantive modifications made by leadership

Following this meeting, leadership and staff will work to make the appropriate modifications to the document and send out to the Committee ahead of the 10/19 meeting, when the Committee will vote on the final version.

Summary of discussion:

There were no questions or comments.

3. Follow-up from 10/5 Meeting

The Committee reviewed the public comment feedback covered on the 10/5 call and held discussion to ensure that all members were up to speed.

Presentation Summary:

Staff briefly recapped public comment themes that the Committee reviewed and discussed on the 10/5 call, including:

- Purpose and position of the white paper
- Balance of principles analyzed
- Thoracoabdominal NRP (TA-NRP) versus abdominal NRP (A-NRP)
- Disclosure and authorization for NRP
- Uncontrolled NRP
- Conclusions of the paper

Summary of discussion:

The Chair explained that the paper is aimed at providing an ethical analysis and not a position paper. The Vice Chair added that there have been concerns regarding the meaning of the paper, if approved by the OPTN Board of Directors, explaining that the paper is not a consensus statement and it is important to stay true to the ethical analysis conducted by the Committee.

A member asked for clarification on the difference between the Committee providing an ethical analysis and providing recommendations, as this may be slightly confusing in the current draft. The Chair responded, stating the Committee can review areas of confusion or concern later on in the agenda, and noted that additional justification was added in some areas to avoid confusion. The immediate past Chair added that as with all ethical analyses, the analysis does not preclude a conclusion, and that there is a difference between prescriptions and conclusions. The original member responded stating that there is still tension between the analysis sections of the document and the conclusions. The Chair reminded members of the scope and charge of the Committee.

A member explained that there are three levels of authority when it comes to NRP: the OPTN, Organ Procurement Organizations (OPOs), and transplant hospitals. This member expressed that it is confusing who has the authority to decide issues related to NRP. Staff noted that this may hint at a broader question of scope and authority of the Committee and its white papers and the OPTN. A member noted that in the case of NRP, the community asked for practical and useful information on the ethical considerations of NRP, and that is what the Committee has provided. Another member responded, stating that an ethical analysis should contain conclusions and that perhaps the conclusion section of the paper should be modified to more accurately adhere to the analysis. This member explained that it is not helpful to the community to have conclusions that simply say that everyone should continue thinking about the issue. Another member asked about expectations of the community, explaining that the paper should respond to community concerns. The Chair added that the white paper will be important and powerful for the community.

Staff recapped the approval process for Ethics Committee white papers and explained that when white papers are presented to the public, usually a couple of slides are included describing the role of the Ethics Committee and the purpose of white papers. When the Multiple Listing white paper was presented to the OPTN Board of Directors (BOD), there was some confusion about the role of the board in approving them and what an “approved” white paper meant. This also came up during NRP public comment, where two commenters asked for clarification on this point. The Chair affirmed the

importance of the Ethics Committee adhering to its charge and scope and the need for community understanding of the purpose and role of the Committee and its work.

TA-NRP versus A-NRP

Members further discussed the feedback and proposed modifications to the paper on the topic of TA-NRP versus A-NRP.

A member noted that the question is whether the difference is in kind or in degree. The Vice Chair explained the difference and concerns with TA-NRP and A-NRP. A member added that the purpose of where ligation occurs is also different between TA- and A-NRP and this is relevant for the ethical distinction.

4. NRP Public Comment (PC) Feedback Review and Discuss Possible Post-PC Changes

The Committee reviewed the public comment feedback not covered on the 10/5 call and discussed, noting areas of potential revision if warranted by the feedback.

Presentation Summary:

Do no harm

Robust feedback was received on the do no harm section of the ethical analysis, and feedback was mixed regarding adherence to the dead donor rule (DDR), its relevance, and ligation of cerebral vessels.

Many commenters pointed out the importance of the DDR as a cornerstone to ethical transplantation and expressed concern that NRP does or may violate it. On the other hand, some commenters debated the ongoing relevance of the DDR and suggested that NRP may be an opportunity to reconsider it. A comment also indicated concern that the ethical acceptability of NRP cannot be addressed properly without a larger, public forum where the broader community is made aware that the transplant community is contemplating a shift away from adherence to the DDR. Feedback also indicated that risks associated with adoption of NRP related to the DDR and other topics under respect for persons can be mitigated with careful standards and protocols. Some comments discussed the possibility of giving NRP donors anesthesia during procurement would lessen non-maleficence concerns.

Several commenters indicated that NRP is not a violation of the DDR, citing the artificial re-establishment of circulation after declaration of natural death, the intent of the donor/next of kin to donate organs, and the intent of the NRP procedure itself. However, several comments received indicated that NRP violates the DDR and/or fails to respect the initial declaration of death. These commenters noted concern that NRP procurement may cause brain death, the possibility of pain or harm to the donor, and the importance of adhering to the DDR for moral and legal reasons.

Feedback on the purpose and ethical considerations regarding ligation of cerebral vessels was varied. Some comments indicated the opinion that ligation of cerebral vessels is a safeguard against the possibility of re-emergence of cerebral function and guarantees that the donor does not suffer. Commenters with this view explained that there is a difference between brain function and perfusion and between a heartbeat and circulatory function, as well as the impossibility of reversing death once a legal declaration has been made. Recommendations to further explain the existing literature on brain blood flow and brain activity were noted.

Yet, many comments across stakeholder types noted concern for the act of ligation of cerebral vessels. Commenters with this view pointed out that ligation of the vessels causes death and/or does not occur

when a donor is legally dead, is not precautionary but instead necessary for preventing the return of brain function, hastens death, and has not been adequately studied and/or ethically debated.

Utility

Many comments discussed possible utility benefits of using NRP and the risks that come with it. Many commenters discussed the improved outcomes, increased utilization, ability to reduce waitlist time, increased control during recovery, and lowered costs with NRP usage. Some commenters pointed out that there may be potential harm from not engaging in NRP and that there are clinicians who believe that NRP is morally obligatory. However, many commenters also discussed the risks that expanding NRP may pose to utility, including concern for negative impact on procurement of kidneys and lungs, concern that the community is overlooking viable ex-vivo alternatives, and the potential negative impact on public trust and donation rates.

Clarifications and Perceived Inaccuracies

Several comments pointed out minor grammatical and consistency concerns. Some commenters also asked for specific clarification not otherwise alluded to in the themes covered above and pointed out certain perceived inaccuracies.

Comments on the Addendum

The Addendum to the paper briefly addresses the implications of the current text of the (Uniform Declaration of Death Act) UDDA and its possible revisions relevant to NRP. Several comments were received on topics covered in the addendum or that have to do with the UDDA that are otherwise outside the scope of the OPTN Ethics Committee and the NRP white paper, such as

- the difference between “permanence” and “irreversibility,”
- suggested and/or possible revisions to the UDDA,
- the need for a unified brain-based concept of death, and
- legal frameworks in the United States as well as broader legal frameworks related to NRP abroad.

Summary of discussion:

Do no harm

A member asked if discussion about the public perception of the relevance of the DDR should be added into the paper, in reference to the public comment feedback that the community may not be aware of the potential shift in attitudes regarding the DDR. Another member added that it is important to include and engage the general community. The Chair explained the rationale behind the discussion of the DDR in the current paper. Another member responded stating that it is important to include the varying opinions of the DDR as it relates to NRP in the paper. The Vice Chair indicated that the existing discussion of the viewpoints in the paper is complete. The immediate past Chair noted that some of the issues raised in public comment are outside the scope of this project, and explained that the important piece for the public is to note where these principles stand in conflict.

A member asked for clarification on the discussion of the use of anesthesia during NRP procurement in the paper. Staff noted that an additional sentence was added by leadership to clarify and be consistent with the executive summary. A member added that they would provide a citation for this section.

Utility

The Vice Chair noted that the utility considerations raised in public comment are relevant, however, the data that currently exists is limited. A member asked about the discussion of ex vivo perfusion techniques in the paper. The Vice Chair responded that the landscape of ex vivo perfusion is changing rapidly and may be outside the scope of the paper. Staff noted that the utility section in the paper references publications on this topic and that the paper will be updated to reflect current understandings and literature.

Comments on the Addendum

The Chair noted that it is important to consider comments submitted on the topic of the UDDA in the context of the scope of the project. A member added that it may be helpful to note the international context a bit more clearly in the text.

5. Review and Consider Edits to NRP White Paper

The Committee reviewed the draft white paper including relevant comments from public comment and suggested edits workshopped by leadership, and members provided suggestions about how to move the draft forward.

Summary of discussion:

Members suggested, discussed, and agreed upon the following modifications to the draft by topic area.

TA- versus A-NRP

The Committee responded to public comment feedback after robust discussion by further differentiating between TA- and A-NRP in several key portions of the paper, including the executive summary, background, and the conclusion. The Committee considers that the difference between TA- and A-NRP is a difference in degree, not in kind, and ultimately, the concerns for do no harm and compliance with the DDR still apply to A-NRP. However, the Committee elucidates the distinction between the two in occlusion processes and purpose and acknowledges that the potential for harm may be more significant with TA-NRP. The Committee made the following revisions:

- Discussion of occlusion of arteries in both forms of NRP was clarified
- Distinction between TA-NRP and A-NRP was more clearly stated
- Why considerations about restoration of circulation are still present for both forms was explained in more detail
- The executive summary and conclusion were updated to reflect the revised discussion in the body of the paper

Do no harm

In considering the divergence of perspectives within the community on the question of the DDR and NRP, the Committee ultimately affirmed its position that there are still outstanding, meaningful questions whether NRP complies with the DDR. Questions as to the importance of the DDR within the transplant community, or modifications to it, are beyond the scope of this paper. As previously noted, the Committee did distinguish that TA-NRP may raise more concern with the DDR than A-NRP in response to public comment. The Committee maintains that A-NRP still raises questions about potential for blood flow to the brain through the spinal cord (even if the potential is less than for TA-NRP) and involves recirculation in the donor after circulatory death is declared. The Committee made the following revisions:

- A brief discussion of the use of anesthesia during procurement was added
- A footnote was updated to discuss the conditions for neurological and circulatory death and their role for NRP
- Clarification was added to the discussion of the act of ligation and its connection to do no harm

Respect for persons

The substance of recommendations (to disclose unique aspects of NRP to donor families) was maintained, and the Committee made the following revisions:

- Language was added to provide additional context to the disclosure recommendations and to acknowledge the challenges OPOs face in informing donor families to the degree to which each particular family desires
- Clarified terms and ensured that consistent terminology is used throughout
- Explanatory language was added to further clarify the term “informed decision making”
- Discussion regarding timing of these conversations was modified and reviewed in response to OPO feedback
- Details of the section were reviewed for consistency regarding the allocation of roles in the approach to disclosure.
- The discussion of ECMO as it relates to uncontrolled NRP was removed as the Committee ultimately found it to be inaccurate according to practice.

Utility

The Committee discussed this feedback and elected to leave this narrative mostly intact, as members felt that the mixed public comment feedback indicated that the paper’s treatment of the utility considerations of NRP on both sides was accurate and balanced. The Committee made the following changes:

- A paragraph was added to further explain utility considerations relating to lung procurement.
- Footnotes and references to current literature were updated throughout to reflect additional literature published on the topic since the paper was issued for public comment.
- A sentence discussing potential moral distress on the part of clinicians who feel NRP is morally obligated to prevent non-utilization was added.

Conclusion

Members highlighted the need for the Committee to be consistent in its analysis, true to the Committee’s charge, clear to the public, and expressed that it is the role of the Committee to describe the ethical considerations involved in NRP, then leave it up to society and the Board of Directors to ultimately decide how to move forward. The Committee elected to make the following changes to the conclusion:

- Remove “proceed, but proceed cautiously.” The text now reads: “the paper concludes that” and then lists the ethical considerations for how the technology may be implemented ethically.
- The bullet point describing concerns about NRP and its consistency with DDR was clarified, and a sentence was added to explain that there may be differences in degree to which the seriousness of the ethical concerns applies to A-NRP versus TA-NRP.

Clarifications and Perceived Inaccuracies

The Committee reviewed feedback in this category and made the following modifications to the text:

- Corrected grammatical errors and ensured consistency and flow

- Added terms to the glossary
- Clarified terms and processes

For example, a public comment received indicated that the description of the process of moving potential donors to OPO recovery centers was inaccurate, and this section was updated accordingly.

Comments on the Addendum

The Committee reviewed comments received on topics covered in the addendum and decided to keep the text of the addendum largely as originally written, noting that while the legality of NRP is outside of the Committee’s scope and charge, it is important to discuss the implications of the current text of the UDDA and its possible revisions for NRP. The Committee added:

- A sentence to note that as of September 2023, the Uniform Law Commission has suspended its deliberations on the UDDA, indicating that the UDDA may not be updated at all for the foreseeable future.

Next Steps:

Staff will incorporate all edits and provide a clean copy to the Committee for review ahead of the vote on October 19th.

6. New Projects

The Committee reviewed the results of a survey sent to members ahead of the call to rank ideas for new projects, and discussed next steps. Fifteen members participated in the survey.

Presentation Summary:

Rating from Survey Results (out of 5)	New Project Idea
2.07	Ethical analysis of split liver transplantation: This white paper would provide a utility-focused ethical analysis of the technique of split liver transplantation, which either provides a left lateral and a right extended liver graft to be transplanted into one child and one adult, respectively, or provides two ‘full’ hemi-grafts-the left side for a small adult or big child and the right for a medium-sized adult patient. The technique is still somewhat rare but provides attractive ways to increase the number of successful grafts, minimize pediatric waitlist mortality, and expand the graft pool. An OPTN analysis of this would be useful for the community. What are the ethical implications of supporting split liver transplantation?
2.80	Examining ethical issues in crowdfunding for transplantation: Crowdfunding raises issues in equity and access to care (when centers make raising funds a criterion for listing). There are also legal issues related to "valuable consideration" for living donors who crowd fund. Transplant centers offer varying degrees of education and support for crowdfunding, but none of them have a formal policy about management of patient crowdfunding, so an OPTN analysis may be helpful. What are the ethical implications of crowdfunding as a way to promote organ transplantation?

2.73	<p>Examining utility considerations in kidney allocation in paired exchanges and larger chains: What are the advantages and disadvantages of different multi-party exchange mechanisms, including varieties of paired exchanges and larger chains in living donation scenarios (also including using deceased donors to initiate paired living donor exchange chains)? What ideas would yield the maximum benefit? What reflect other ethical considerations?</p>
3.20	<p>A white paper ethical considerations in xenotransplantation: Given the recent cases of xenotransplantation and calls by the Maryland group for additional cardiac xenotransplantation candidates, the field appears to be evolving rapidly. Although there are numerous developing societal guidelines regarding ethical considerations in xenotransplantation, an OPTN white paper would have particular standing in this area. This white paper would ask: What are the ethical considerations which bear on the question of whether we should engage in xenotransplantation to address the organ shortage?</p>
3.13	<p>Examining ethical implications of altruistic donation in certain living donation scenarios: Analysis of ethical implications of altruistic donation in cases that may require more scrutiny, including accepting organs from anonymous altruistic donors with history of mental illness or accepting multiple organs from the same altruistic donor (such as partial liver donation following kidney donation).</p>
3.86	<p>Examining ethical considerations in access to living donation: This white paper would undertake an analysis of the ethical implications of equitable access to becoming a living donor. The project would be utility and equity focused, and consider the difference between “removing disincentives,” on the one hand, and “adding incentives,” on the other, in promoting living donation. The paper would refer to some recent legislative proposals from different states to illuminate the conceptual difference between “removing disincentives” and “adding incentives.” One of the ideas here is that living donation is a privilege, which beckons the question: how can we make this privilege more accessible to groups who traditionally do not participate in living donation as frequently?</p>
3.20	<p>Providing ethical guidance to assist transplant programs in creating policies and protocols around vaccinations: This white paper would undertake an ethical analysis of the considerations underlying vaccinations in transplantation to be used as a resource for transplant programs when developing policies regarding vaccinations. What specific vaccinations and under what conditions (e.g. pandemic conditions) vaccinations would be recommended/mandated is something additionally to discuss upon considering the project proposal for this white paper. What are the ethical implications of creating vaccination recommendations or requirements as part of eligibility to receive an organ?</p>

Summary of discussion:

The Chair noted that the access to living donation project is an area of personal interest and that the Board would be receptive to this project from a utility standpoint. The Chair also asked members to consider which project they would be most interested in working on. A member asked if the living

donation access idea would address directed living donation based on religious affiliation or ethnic group, and the Chair responded that it could be considered for inclusion in the project. Another member stated that the living donation access project could connect to the kidney chain project idea. The Chair agreed. A member commented that minority access to becoming a living donor is a big focus at their center.

On the guidance for protocols around vaccinations idea, a member stated that this may be a politically charged topic. Staff noted that the OPTN Patient Affairs Committee is also looking into a project that may connect to vaccination guidance. A member stated that taking up this issue now, after programs have already had to create vaccination policies, would not be the correct timing. The Chair shared some considerations that the paper could discuss, if the Committee were to move forward with the idea.

On the xenotransplantation idea, a member commented that it is similar to NRP in that the transplant community is starting to engage in a practice that has not undergone a full ethical analysis. Staff noted that at this time, xenotransplantation is not within the OPTN's purview.

Next steps:

The Committee will continue to discuss these new projects in upcoming meetings.

7. Closing Remarks

The Chair, Vice Chair, and staff thanked members for their participation and attendance.

Upcoming Meetings

- October 19, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - Bob Truog
 - Carrie Thiessen
 - Erica Stohs
 - Jen Dillon
 - Shelia Bullock
 - Keren Ladin
 - Andrew Courtwright
 - Sanjay Kulkarni
 - Thao Galvan
 - Lois Shepherd
 - Megan Urbanski
 - Ehab Saad
 - Felicia Wells-Williams
 - Sena Wilson Sheehan
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - None
- **UNOS Staff**
 - Cole Fox
 - Kim Uccellini
 - Kristina Hogan
 - Rebecca Murdock
 - Kieran McMahon
 - Joel Newman
- **Other attendees**
 - Laura Butler