OPTN Operations and Safety Committee
Meeting Summary
November 7, 2024
Conference Call

Kim Koontz, MPH, Chair
Steven Potter, MD, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via WebEx teleconference on 11/7/2024 to discuss the following agenda items:

1. Overview and Discussion: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement Public Comment Presentation: Promote Efficiency of Lung Donor Testing

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

1. Overview and Discussion: Standardize Practice in the use of Normothermic Regional Perfusion (NRP) in Organ Procurement

The Committee reviewed and finalized recommendations in response to the OPTN Executive Committee's resolution[1] for the Committee to address Normothermic Regional Perfusion (NRP) practices. Committee leadership compiled the recommendations discussed during the Committee's October 24th meeting[2] to develop the following recommendations for the Committee to review, provide feedback, and finalize:

- **Guidance**
  - Guidance would address the following topics:
    - Key personnel in planning and performance of NRP
    - Pre-procurement huddle/communication plan
    - Technical standards for procedure
    - Credentialing Standards/Experience Levels
    - Quality Control/Peer Review
  - Sponsoring Committee: Operations and Safety (with collaboration with other OPTN Committees/stakeholders)
- **Policy**
  - Donor Authorization: incorporating potential utilization of NRP as an organ recovery method in the standard DCD authorizations utilized by OPOs
    - Refer to OPTN Policies 2.2: *OPO Responsibilities* and 2.15: *Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* as potential framework/template
    - Sponsoring Committee: Operations and Safety

[1] OPTN Executive Committee Meeting Summary, September 26, 2024.
[2] OPTN Operations and Safety Committee Meeting Summary, October 24, 2024.

    - Pre-operative huddle/time-out: a huddle or time-out process between all team members participating in the NRP procurement at the donor site and prior to withdrawal of life-sustaining treatment (WLST)
        - Policy Recommendation: The provider performing WLST should be identified in the pre-procedure huddle, must be a physician or a physician's designee. and must have expertise in end-of-life care protocols and symptom palliation.
        - Refer to OPTN Policy 2.6: *Deceased Donor Blood Type Determination and Reporting* as potential framework
        - Sponsoring Committee: Operations and Safety
    - Intra-operative huddle/time-out: a huddle or time-out process between all team members participating in the NRP procurement at the donor site and prior to withdrawal of life-sustaining treatment (WLST)
        - Policy Recommendation 1: A surgical "pause" or "time-out" must occur to provide verbal confirmation that the brachiocephalic vessels have been appropriately occluded and that cerebral reperfusion has been rendered infeasible (TA-NRP)
        - Policy Recommendation 2: A surgical "pause" or "time-out" must occur verifying that the aorta been appropriately occluded and that in situ perfusion is only occurring in the abdominal cavity (A-NRP)
        - Refer to OPTN Policy 2.6: *Deceased Donor Blood Type Determination and Reporting* as potential framework
        - Sponsoring Committee: Operations and Safety
- **Data Collection**
    - Defer data collection and documentation guidelines and policies to the OPO Committee
    - Recommend additional data elements should be collected and uploaded to the OPTN Donor Data and Matching System for NRP cases
        - The time of administration and dose of heparin administered
        - The time that WLST was performed the time after WLST that the donor's systolic blood pressure (sBP) drops below 50 mmHg until the start of NRP. This period defines the sBP50-interval.
        - The stop and start times for the NRP run (aka the NRP run-time).
        - For TA-NRP only: The autologous perfusion period
        - Cross-clamp times for the various organs
        - Lactate levels drawn from the NRP circuit and the time of those collections
        - The NRP flow rate in liters/minute

<u>Summary of discussion:</u>

A member asked if the policy recommendation for the pre-operative huddle/time-out was implying that provider would be included or just named. The member continued by commented that having that specific expertise outlined would be challenging for OPOs to fulfill that requirement.

The Committee Chair clarified that the focus of this policy recommendation was the communication huddle. The intent was to have the provider named in the huddle; most of the times, the provider actually performing the withdrawing is not included in the huddle. The Committee chair stated that this recommendation was meant to be flexible by outlining physician or physician's designee.

The Committee Vice Chair stated that the language chosen was to be more open ended. Expertise is not defined in the policy or elsewhere in the bylaws or policy so it was not thought that the requirements would be too stringent in requiring the person who is performing the withdrawal of life sustaining

therapy (WLST) should be familiar with what kind of things could be administered to the donor and what could not be (i.e. symptom validation). The Committee Vice Chair stated that this language was left open ended and clarified that you don't have to have a physician (they can designate someone to be there), this would allow for that flexibility as well.

A member stated that in the context of NRP, the language should be clearer. The member further explained that they have pre- operating room (OR) huddles with the physician or physician designee but those two never meet. The member stated that there should be clarification as far as what huddle is being outlined – NRP huddle or pre-OR huddle. The Committee Vice Chair clarified that the proposed language is not saying that the person performing must be in the huddle, but the team that's doing NRP has to know who is going to be doing the WLST.

Another member asked that in clarifying this, the team that is doing the NRP is the procuring team – why would they need to know who is withdrawing and doing the palliation as these are two separate things.

The Vice Chair provided an overview of the recommendation document that was developed. The Vice Chair explained that the approach is agnostic on what ends up as guidelines versus (vs) policy. The Committee was made aware that what is being presented are recommendations; the Committee is not committed to the items presented as this will be reported out and decided by the OPTN Executive Committee on the next steps.

The Vice Chair summarized that what was envisioned was that guidance would outline two huddles. Given the unique challenges of NRP, there would be two huddles – one huddle would be prior to the disparate teams transporting to the donor location. There should be a virtual huddle among those team members. The second huddle would be at the site prior to WLST. Additionally, the document further details what kind of criteria should be covered in those huddles. This would not be recommended as a policy, but rather guidance. From a policy perspective, the Committee would be recommending that a huddle would be required.

The Committee Chair added that it was understood that most OPOs are already holding a pre- huddle. A policy to say that a huddle should take place – most members are already doing this currently. The Vice Chair agreed with this and clarified that the intention is to provide some standards and guidance, but not to create additional barriers to the performance of this new technique. The Vice Chair continued by stating that these are necessary things for NRP. If you don't have a meeting before people transport to the site, then you don't know who is bringing the tools you need. There needs to be some clarity on how much warm time is going to be tolerated, how long would NRP runs be, how will cannulation be done, etc.

A member agreed with this and added that if these are guidelines, they would be in agreement of this. Having guidelines vs. policy are two different things. The Vice Chair agreed in being cognizant of this and clarified that some of the things that were suggested in policy are not all the items but rather just outlining the fact that a huddle of some sort would be required.

The Committee Chair stated that the language being recommended may need to be modified. For the pre-procedure huddle, the language "The provider providing the withdrawal should be identified in the pre-procedure huddle" could be edited based on the feedback provided. The Vice Chair stated that this language was meant to be on site so when you're on site and performing withdrawals, you should know who the person withdrawing support is. The Vice Chair clarified that this was not meant to be in the pre-transportation huddle.

A member re-emphasized concern around the expertise in end-of-life protocols and palliation. From the OPO perspective, OPOs are not choosing who the hospital decides is qualified to do the withdrawal of life support or the administration of medications. The wording being presented sounds like it is the responsibility of the OPOs to make sure they are qualified and have expertise in WLST.

Another member agreed with this and stated that OPOs do not assign or discuss what type of palliative medication will be administered. The Vice Chair agreed with this and suggested rewording the language to, “The provider performing WLST should be identified in the pre-procedure huddle, must be a physician or a physician’s designee”. The Committee agreed with this rewording.

A member suggested that the donor preparation and dripping occurring prior to withdrawal should be in guidance versus policy; at their OPO, about 95% of their withdrawals are done in the post- anesthesia care unit (PACU) and not in their OR. The Vice Chair clarified that this would be in guidance. The Committee was alerted that the documented recommendations are mostly guidance unless specified differently.

The Committee Chair added that the language being reviewed are not the final language that would be used. The language being presented could be subject to change with additional review and discussion. The Vice Chair stated that this is a starting point and that the Committee would be provided with more guidance from the OPTN Executive Committee on next steps.

The Vice Chair continued by reviewing additional guidance where all team members performing NRP should commit to performing the NRP procedure until the maximum time from WLST or until arrest dictated prior to withdrawal's therapy has been a reach. So that means, in other words. A member agreed with the inclusion of this language.

The Vice Chair reviewed the technical standards recommendation around potential policy language where a surgical pause or timeout must occur to provide verbal confirmation that the that basically cerebral reperfusion's not going to be feasible.

A member voiced support and stated that this seemed reasonable. The member added by suggesting there being some guidance for having a reassessment or continuous assessment of the occlusion still being in place. The member stated that they’ve experienced where there were double clamps and there was concern that a clamp may slip so continual assessments can help avoid this and may be helpful to have guidance.

The Committee Chair agreed with this and stated the intent of not being too prescriptive about how the occlusion would happen. The Committee Chair continued by stating that based on some of the feedback received from other recovery surgeons who have done multiple NRP cases and about anatomy and trying to make sure that there is flexibility to address any anatomical differences and variances and pediatric cases versus adult cases, but still making sure that process happens.

A member asked if there is a need to specify the need to assess recirculation as a possible concern. The Vice Chair stated that there was thought into this, however, the intention of these recommendations is to not be too prescriptive. Transcranial doppler, for example, is a tool that would be helpful, but it may not be accessible across programs. After consulting with multiple neurosurgeons and vascular neurosurgery interventionalists, it was elected not to specify any further. The Vice Chair added that this does not preclude ongoing monitoring with something as simple as a pulse oximetry.

A member suggested collaborating with the Association of Organ Procurement Organizations (AOPO) Credentials Information Network (ACIN) to see if there may be a place to add NRP in their credentials. This would allow OPOs to be able to go into ASIN and identify those who are credentialed. It would be

the OPO's responsibility for those that they sponsor to make sure that their credentials are documented there.

The Vice Chair stated that the question would be whether to put an organization in guidance for an OPTN document or not. The member continued by stating that the language should mimic the language that is outlined for other types of procurement. The OPTN Contractor staff stated that they would investigate this further and if there is language around this, when the project begins, the language would be reviewed to ensure uniformity.

The member stated that they are audited on this so if they were active at the time of the recovery in that system, there should be some sort of correlation.

Another member asked how this would be justified or how it can be proven that whoever is doing the NRP has had five cases before that? The member agreed with the suggestion of including credentials in ACIN because asking someone is different than having written proof.

The Vice Chair clarified that the guidance is not asking for OPOs to ask for credentials, but instead is setting up a framework with some expectations through guidance. The member continued by stating that going forward, you would want people trained in NRP. The Vice Chair asked what the action item should be.

The member agreed in not wanting to be too prescriptive but there should be some sort of certification or proof of proficiency with NRP to prevent any incident.

The Committee Chair stated that there was discussion on the oversight of credentialing and there was a suggestion of having some potential discussions with AOPO in having the ability to have something documented. There are other third party agencies that are not addressed as they are outside of OPTN membership.

The member stated that their understanding is that no matter who does it, they would still need to be credentialed by ACIN. The Committee Chair agreed with this point.

The OPTN Contractor staff also reviewed the data collection recommendation and updated the Committee on the OPTN Executive Committee's recommendation of combining efforts with the OPTN OPO Committee to avoid duplicating efforts on their work. The OPO Committee liaison stated that the Machine Perfusion Data Collection Workgroup (WG) just began their work and are beginning their focus on NRP data. The OPO Committee is requesting any additional feedback for their consideration to include in these efforts.

There were no additional comments and questions. The meeting was adjourned.

<u>Next Steps</u>

- The Committee's recommendations will be modified based on the feedback provided during the meeting
- The recommendations will be presented/reported out to the OPTN Executive Committee where the Executive Committee will review and determine which project recommendations (and in what sequence, if applicable) will move forward
    - The Committee was notified that this may affect the OSC's current *Donor Testing Requirements* project depending on the Executive Committee's feedback

Upcoming Meetings

- Thursday, December 19, 2024 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Steven Potter
  - Amanda Bailey
  - Annemarie Lucas
  - Anne Krueger
  - Bridget Dewees
  - Elizabeth Shipman
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Laura Huckestein
  - Megan Roberts
  - Norihisa Shigemura
  - Sarah Koohmaraie
  - Mony Fraer
- **SRTR Staff**
  - Avery Cook
- **HRSA Staff**
  - Marilyn Levi
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Cass McCharen
  - Robert Hunter
  - Kaitlin Swanner
  - Kayla Temple
  - Kerrie Masten
  - Laura Schmitt