OPTN Operations and Safety Committee
Meeting Summary
January 23, 2025
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 1/23/2025 to discuss the following agenda items:

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

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

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

The Committee reviewed a draft of the Committee's guidance document targeted to go out for special public comment in March. The guidance document addresses the following topics:

- Consent/Authorization
- Pre-Operative Communication
- Intra-Operative Communication
- Technical Standards for the Procedure
- Key Personnel

The discussion included guests who were identified as subject matter experts (SMEs) in NRP through their experience and authorship in publications.

Summary of discussion:

A SME suggested a revision to the Key Personnel section. It was noted that the document currently lists experienced transplant surgeons; it was explained that there are many surgeons (transplant surgeon or prior transplant surgeon) who are performing NRP as well as surgical specialists that could be trained. The SME voiced concern in limiting the term to transplant surgeon and suggested revisions in language that would include a trained surgical specialist with evidence of training and competency vetted through the credentialing process. Another SME agreed with this added a suggestion of replacing "transplant" with "recovery".

The Vice Chair commented that there should be some clarity from the community as well as alignment with the American Society of Transplant Surgeons (ASTS) colleagues. The Vice Chair continued by stating that there are capable technicians performing organ recovery, but to be in alignment with existing guidance from professional societies, the term "surgeon" would be used instead of "transplant surgeon".

A SME commented that from an organ procurement organization (OPO) perspective, there are different ways this practice is obtained and there are some highly skilled, trained staff who are credentialed in

various ways (i.e., ACIN and transport center accreditations). The SME continued by voicing concern that if the requirement only mentions surgeons, it will make it challenging to broaden expertise with the variations seen in the field.

The Chair stated that at their program, they have someone in their organization who would be capable of doing an NRP cannulation (a trained surgical physician's assistant (PA)). The Chair suggested changing the language to trained recovery professional and then having some sort of system or recommendations for a robust credentialing process specific to those individuals that may not be trained recovery surgeons.

A SME commented that this format is not that of the ASTS; those guidelines are similar and overlapping but it is not thought the OPTN would have to be married to someone else's guidelines if they are not in line with what the OPTN's mission is, which is to maximize the number of organs that get recovered safely for transplant. This does not require someone with an ASTS fellowship. The SME continued by stating that key personnel must include someone from an OPO.

The Vice Chair agreed with this and stated that it is assumed this is the case – for most programs, at least one of the recovery assistants is going to be from the OPO. The Vice Chair noted that further down in the draft document, there are multiple models and approaches that NRP teams can take – they can outsource the entire process, or they can develop a holistic program. The NRP surgeon can be an OPO employee or can be from a transplant program. The same is true for the recovery assistance and the perfusionist.

A SME replied by stating that there should be consistency with what the guidance document and AST documents say for the optics of things with the knowledge that these are living documents that can change in the future. The SME continued by stating in writing the AST census statement, there was discussion about this, and it is thought that there are capable staff who can do this who are not surgeons. The SME continued by stating that to maintain public trust, there should be caution on how the OPTN guidance is messaged and in alignment with other documents.

Another SME commented that the issue is that this is guidance (versus policy) and if guidance is going to say that there needs to be an experienced surgeon, there is also a need to include an experienced perfusionist. Perfusionist and technicians are completely different and there are some technicians who can do NRP. In discussing best practices, and following the national perfusion guidelines, it is an NRP trained and experienced perfusionist, not a technician. Another SME agreed with this and added that there a technician does not have the equivalent experience to a perfusionist.

A SME suggested the Committee consider the policy implications as their understanding is that this project may expand to policy and using the guidance as a framework.

Another SME shared their thoughts around an OPO representative being a part of the key personnel by suggesting that it is imperative to include the OPO coordinator as part of the key personnel given the fact friction points associated with NRP, and that communication is essential. The NRP process starts upstream regarding communication with the caregiving team to include the attending physicians and the nursing staff as well as the OR staff. These are also the people who are facilitating the pre-arrival huddle and handling any sort of challenges/obstacles when it comes to allocation and competing technologies. The SME suggested consideration to include not only OPO representatives but also senior leadership.

The Vice Chair agreed to include OPO coordinator and suggested not including OPO senior leadership because it may put teams in a difficult position if senior leadership is unavailable.

A SME asked if the guidance is setting aside the question of what constitutes adequate training. The Vice Chair stated that this is addressed later in the document (under the Credentialing Experience Level section). The Vice Chair further explained that the guidance is not trying to relitigate what adequate experience should be for a perfusionist, but it does address the concept of how a team gains proficiency with NRP and what should that training slope or experience look like.

The Committee then reviewed the Pre-Procurement Items section that recommends that there be two huddles or pre-procurement communications for the team. One huddle would happen before transportation to the site and the second huddle would happen immediately at the site shortly before withdrawal of life sustained therapy. A SME agreed that this is the current practice at their program and that it is the current practice in doing the pre- and post- huddles. The SME continued by commenting a challenge with the language in the section as there are often times where transplant programs do not attend the huddles and suggested the language in the guidance document be changed from "must" to "should". Making sure there is a representative on these calls is key, but as an OPO, all that can be done is to set up the conference calls and voiced uncertainty in strength of mandating this.

The Vice Chair agreed with this and stated that where language states "must" will be changed to "should" since this is guidance and not a mandate. A SME commented on their belief that the huddles are essential in terms of the success and outcome of these procedures for them to go smoothly. The SME continued by stating that last year, their program held 147 of these cases and did a zoom call on all of these cases; this is part of their condition of acceptance. The SME explained that as part of their huddle, they want a person with decision making capability from the transplant program on the call which is most often either the attending position or the position who is coming out to do the recovery. The huddle is where the teams review the donor, go through the surgical approach and work out any differences with regards to processes. The SME continued by stating that from their experience, they had not had the experience of people not coming to the call and suggested there being a way to emphasize the importance of this call in the guidance document.

The Vice Chair replied by suggesting removing the wording of "must" for all of the guidance points, but keeping "must" as it pertains to stating that pre-procedure huddles must occur. This would address the concern of listing who would need to be on the call but rather that there needs to be a call.

The Chair added that this is consistent with their practice as well and that they also have everyone join to participate. There were no additional concerns voiced related to this section.

The Vice Chair added that the guidance also includes specific questions that could be considered and in meeting with multiple SME's, the section provides an accurate assessment of those processes. A SME questioned if anesthesia is needed. The Vice Chair clarified that anesthesia was included with the assumption that anesthesia are the staff who will withdraw live sustained support. The SME responded that in their experience, anesthesia is not usually involved at all.

Another SME agreed with this and stated that with abdominal, they don't use anesthesia, and they have had some cases where the operating room (OR) time changed based on anesthesia availability when it wasn't needed. The SME continued by suggesting there being more specificity to the question posed of who would be responsible for blood to be available. The SME stated that they believed most NRP programs want blood checked into the room. It was suggested to include language that blood is checked in in the room at time of the procurement; this is probably the number one delay that they have come across.

Another SME noted that for pediatric NRP, anesthesia is needed and should be included in the guidance. A SME clarified that this should be included as a question – "Do you need anesthesia or not?"

Another SME further explained the reasoning in including this question. Typically, anesthesia is done at the donor hospital and they also had experiences where they would have anesthesia help with the case, but heart may not require it. This varies on the transplant program requirements as well as the organs being recovered. It was agreed that the question of whether anesthesia is needed for the recovery as well as who would provide it should be included in the questionnaire.

Regarding the question, "What are the acceptable warm ischemic times (WIT) definitions and parameters for the centers accepting the organs?", a SME commented that in cases of thoracoabdominal normothermic regional perfusion (TA-NRP), if the thoracic cannulation cannot be accomplished, there should be discussion about at what point it would be converted to a standard DCD recovery through the abdominal organs. The Vice Chair summarized this edit to being that there be contingency plans in for conversion to standard DCD if thoracic cannulation cannot be achieved. The SME agreed with this edit.

Another SME suggested using the term "rapid recovery" rather than "standard"; NRP is standard in some places.

A SME commented that there should be a negotiation of pump time because there are some cases where there is a conflict between the thoracic team and the abdominal team in their desires for how long they stay on pump. The Vice Chair agreed with this.

Another SME voiced agreement in this and added that this is seen all of the time; thoracic teams often want shorter periods of time, and the liver teams want longer periods of time. Ideally, during the pre-arrival meeting prior to getting to the donor hospital is where this is negotiated, and an agreement is made between the two teams. The SME continued by stating that it would be ideal to have some suggestions as to if an agreement cannot be made (whether in this guidance document or not), where do you settle the time to satisfy both the thoracic and the abdominal teams.

In regard to the section related to authorization, a SME commented that "informed consent" is the term that should be used (versus authorization) in terms of invasive procedures prior to withdrawal of life sustaining treatment. Anything to do with organ donation and postmortem procedures would go under authorization because it is gift law rather than medical intervention.

The Committee reviewed the "Technical Standards for the Procedure" section that addresses that multiple models for construction of an NRP team are appropriate and the choice of model utilized should be determined by the NRP team based on their training levels, degree of institutional support, and skills available to the team. The Committee was asked for input on this section.

A SME suggested including something in guidance that at some point there should be a provider responsible for withdrawal should have some experience with donation after cardiac death (DCD) donation. This may not be accessible due to resources across hospitals in the United States, but it may be something that could be advised in the guidance.

The Vice Chair responded by voicing alignment in this suggestion but explained that they left this out to avoid creating any liability for teams at smaller community hospitals who may not have limited resources. The Chair agreed with this and added that from an OPO perspective, they do many cases in small hospitals where their resources are limited. It would be difficult to reach a recommendation not knowing what the hospital is able to provide.

The Committee then reviewed the "Prevention of Cerebral Reperfusion during TA-NRP" section. The Vice Chair asked for feedback on this section and voiced their concern as this gets at the heart of the critical comment received; the more thorough you make this prevention, the more difficult you make the performance of the NRP. The Vice Chair summarized that the section would include guidance that

multiple methods of occlusion are appropriate. Occlusion with a single clamp is not recommended because of risk of dislodgement during the run. Clinical circumstances may dictate if only one clamp is utilized; it was further explained that this was included, for example, for small pediatric donors where it may be challenging to get two clamps on.

A SME asked where this guidance document should include the need to vent. The Vice Chair agreed with this point and its importance. The venting and then running back into the circuit can be important to decrease transfusion requirements. The Vice Chair stated that this was not included due to the uncertainty of being this specific in guidance.

Another SME shared their perspective on venting and stated that it can be done with essentially zero effort, and it causes no hassle. Their personal thoughts are that physiologically, it is probably not necessary, but until there is more scientific evidence that it is not necessary, it causes such little hassle, it should be included in guidance. The SME suggested anytime the clamp is mentioned, to add "clamp and vent".

A SME inquired that if the guidance is going to include specifics around how the brachiocephalic vessels are clamped, is there a need to have a specific around the way the descending thoracic aorta is clamped and vented? The Vice Chair stated that this was included in a separate section for abdominal normothermic regional perfusion (A-NRP). The SME also shared that "occlude and vent" or "staple and vent" are also reasonable terms to use.

The Chair asked that if clamping and venting is being included in guidance, is there a need for an additional method of monitoring for inadvertent or unintended reperfusion in addition to venting, or is this accomplishing the goal with venting?

A SME stated from their perspective, if you adequately vent and make the blood pressure inside the vessel zero; zero blood pressure equals zero flow so there would be no unintended cerebral perfusion. Another SME agreed with this and stated that this is one of the methods that is acceptable. The SME continued that there could be other things; for example, the SME shared that they use an upper extremity arterial line (A-line) in A-NRP before they get into the chests which is a way of monitoring until you clamp and vent. The SME stated that in guidance it should say that it should be in place and wouldn't qualify with venting or not because the recommendation should be that venting should be done in every case as possible.

Another SME commented that venting should be verified in some way by the OPO personnel. This should be stated to make sure that it is done and not assumed and documented at the time. A SME agreed with this and stated that this recommendation should be made at the same time as the surgical pause for the occlusion. The Vice Chair agreed and stated that this would be communication from the surgeon to the OPO representative in the room who could document this.

The Committee then reviewed the "Prevention of Thoracic and Cerebral Reperfusion during A-NRP" section. A SME voiced no concerns with the section and commented adding venting per the previous discussion of including this language with "clamping". The SME commented on the statement, "the aorta must be occluded prior to initiation of regional flow via the TA-NRP" and suggesting changing TA-NRP to either A-NRP. The SME stated that NRP could even be used since the circuit is the same.

The Chair stated that for the surgical pause, it should be separated as it should happen with both abdominal and thoracic. A SME asked for clarification on the operational component of the surgical pause if a surgeon has clamped and vented and called this out. Another SME stated that this would be the surgical pause and explained that the surgical pause would be that the surgeon verbally stating that they have clamped, vented, and can proceed with NRP. The Vice Chair clarified that this is the accepted

term but does not mean that there is a pause in the process. The SME summarized this a bit further by stating that the surgical pause is verbal confirmation of clamping and venting prior to the initiation. The Vice Chair stated that the intent is to ensure that everyone in the room understands what is going on throughout the process.

The Committee then reviewed the "Credentialing Standards/Experience Levels" section. A SME commented that this is keeping with the ASTS guidelines. The Vice Chair confirmed this was the case. Another SME stated that for the "success" part, instead of saying establishing and maintaining, there should be something about adequately perfusing the organs. The SME further explained that you can be on NRP and not adequately perfusing. The SME mentioned that from their experience they have had instances where they have had these arguments with some OPOs with perfusion companies that are not necessarily doing a good job with perfusing the organs even though they are technically putting things on pump. The SME suggested the wording be changed to "Establishing and maintaining adequate organ perfusion with the NRP circuit".

Another SME asked if there should be a definition of "adequate". The SME explained that they are looking at flow rates and know there is documentation or requirement of flow rates, but if the flow is below a certain point they are clamping and going to rapid recovery because they are not adequately perfused. Should there be a range of the flow rate that would determine adequate perfusion?

A SME replied that the true measure of perfusion if the oxygen delivery and extraction. If you are flowing at two liters (L) but have a hemoglobin of 10 and an FIO_2 two of 100 with an SVO_2 of 500, then the organs are probably being adequately perfused adequately even though the flow rate is low. On the other hand, if you are flowing at five, but your hemoglobin is 3, the organs are not adequately being perfused. Although flow rate is important, it is not necessarily the only thing. The SME stated that the guidance should be left open in terms of adequate perfusions of organs. In discussing the end goal of NRP, it is perfusion and not just the circuit.

Based on the Committee's discussion, the Vice Chair summarized the edits to being, "success in the setting is not termed by allocation of transplantation the organ, but rather by adequate perfusion of the organs via the NRP circuit.

The Committee reviewed the Quality Control/Peer Review section. A SME asked if transplant hospitals track the quality of rapid recovery DCD and machine perfusion DCD and donation after brain death (DBD)? The SME was wondering if there should be consideration of ensuring these recommendations are across the board. The Vice Chair stated that the outcomes are tracked meticulously but the focus is not on the performance as it is not part of the rubric. The Vice Chair stated that this section addresses the critical comment to have some level of quality control and record keeping.

A SME asked why TA-NRP was being called out for credentialing and not including A-NRP as well. Another SME agreed with this and commented that the guidance of needing five successful NRP procurements for credentialing should not just be a TA-NRP requirement and should also be required A-NRP.

The Vice Chair asked for clarification of the suggested edits and asked if the expectation is for five successful NRP – if you want to do A-NRP, should you have done five A-NRPs or could there have been five TA-NRP and/or some combination of TA- and A-NRP. A SME stated that it is the team dynamic of being able to have somebody who can cannulate and communicate and somebody who can run the perfusion device. The location of where the cannulas go is not the distinguishing feature of being successful or unsuccessful in NRP.

The Vice Chair suggesting removing TA- and A- NRP and leaving the statement to just read 5 successful NRP.

A SME commented that there is not a mention of third-party companies and asked if they are doing NRP, should there be a quality guideline for them. The Vice Chair read the statement that was included in the guidance, "Third-party providers of perfusion or recovery services may be at risk of loss of OPO privileges to perform NRP recoveries if conduct or technical issues arise and are not remediated". The SME agreed with this statement.

Another SME provided additional feedback with the guidance of five successful NRP procurements for credentialing. The SME stated that doing five A-NRP would be different than five TA-NRP. The SME stated that if a surgeon were to say they have performed five A-NRP and are ready to do TA-NRP, there would be more concern for this than if a surgeon did five TA-NRP.

Another SME stated that one of the confusing things about the definition of what TA- and A-NRP is, is about what is being perfused and not where things are being cannulated. This is important because you can do a TA-NRP with an abdominal, femoral, or central cannulation. An A-NRP can be done with these three different cannulations as well. The SME suggested there being clarity in the guidance about what TA- and A-NRP are. The difficult part about TA-NRP is not the cannulation but rather it is making sure that you clamp the vessels correctly which is something abdominal surgeons are not trained in and can cause concern. There needs to be clarity on what these two different techniques are, what defines them, and then it should be specified on the credentialing part on the TA-NRP concern. The SME will provide some definitions for consideration for the guidance.

A SME stated that there should also be some thought (specifically for OPO leadership) that when coordinating an NRP case, there should be an OPO representative who has some degree of experience on the team. This should not be a traveler who has shown up in the service area and is suddenly putting together an NRP case given the complexity of communication and the friction points surrounding this process. The SME added that this is about ensuring trust and recognizing there are sensitivities surrounding this process. The SME suggested consideration of recognizing there is variability in practice regarding the hands-off period. The SME stated that in their area, the hands-off period is five minutes, where in other areas the hands-off period is two minutes. Also, there's ensuring within that time period that there is no auto resuscitation; who is confirming the fact that there is no auto resuscitation? Should it be spelled out that this is a member of the caregiving team who stays around to ensure that the heart has not restarted? The SME voiced their opinion that this should not be a representative from the OPO as it seems to be a bit of a conflict. The SME stated that this is some thought as to whether the guidance document should include specificity to this extent.

There were no additional comments or questions. The Committee and SMEs were asked to review the draft guidance document and prepare feedback for additional consideration as the Committee works to continue editing and finalizing the guidance document.

<u>Next Steps</u>

- The Committee and SME's/stakeholders will review the draft guidance document and provide additional feedback for consideration.

Upcoming Meetings

- Thursday, February 20, 2025 (Teleconference)
- Thursday, February 27, 2025 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Steven Potter
  - Anja DiCesaro
  - Anne Krueger
  - Annemarie Lucas
  - Bridget Dewees
  - Kaitlyn Fitzgerald
  - Laura Huckestein
  - Megan Roberts
  - Norihisa Shigemura
  - Sarah Koohmaraie
  - Mony Fraer
- **SRTR Staff**
  - N/A
- **HRSA Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Kaitlin Swanner
  - Kelley Poff
  - Kerrie Masten
  - Laura Schmitt
- **Guests**
  - Anji Wall
  - Carrie Thiessen
  - Deana Clapper
  - Jennifer Muriett
  - Jennifer Prinz
  - John Edwards
  - Jordan Hoffman
  - Julie Spear
  - Kristine Browning
  - Marty Sellers
  - Matthew Hartwig