OPTN Operations and Safety Committee
Meeting Summary
February 20, 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 2/20/2025 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:

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

Summary of discussion:

The Chair reviewed the guidance document draft with the Committee and highlighted some of the edits that had been made since the last Committee call (and with additional consultation with the subject matter experts (SMEs)).

The OPTN contractor staff provided the Committee with a tentative timeline for the special public comment period of March 18 – April 16. The Committee was notified that the guidance document would need to be reviewed by the OPTN Policy Oversight Committee (POC) as well as the OPTN Executive Committee for their approval for the guidance document to move forward to special public comment. Should there be and changes to this tentative timeline, the Committee will be updated.

The Chair began review of the guidance document draft as follows:

Background: There were no changes made to this section.

Key Personnel: From the previous Committee discussion, there was feedback on using the term "transplant surgeon" versus (vs) "recovery surgeon". There was discussion that transplant experience surgeons that are working for organ procurement organizations (OPOs) that are trained. Based on this feedback, the language was changed from "transplant surgeon" to include recovery surgeons and a statement to further clarify that staff doing the recovery have the right expertise.

The OPTN contractor staff added that with acknowledgment of the various roles and staff that are not necessarily listed in the document, there is language that was added that the key personnel is not limited to the list within the document. The Vice Chair agreed with this and added that the question came up about Advanced Practice Providers (APPs) that are trained to perform recoveries and if they would still fall within the recovery personnel that had adequate expertise. It was agreed upon the SMEs and leadership discussions that this would include those personnel as well.

The Committee Chair summarized discussions with the SMEs about including words "must" and "should" in the guidance. For example, it was determined that for discussions around the pre-procurement communication huddle or the pre-procurement communication huddle the term "must" should be used to emphasize how critical it is for these huddles to occur. Throughout the document, there are some strategic situations where "must" is used vs "should".

Pre-Procurement Items: A member asked a question about the communication huddle and pointed out the statement, "the presence of accepting transplant program decision makers on the pre-transportation call is critically important". The member explained that in thinking about their program, one of their surgeons is doing the abdominal NRP, who would be expected on the call if the accepting transplant program is not sending anyone – if they are recovering the liver for another program, is the accepting program still required to be on this call?

The Vice Chair confirmed that this would be the hope because the thought is that they would be the ones to decide things like the length of time that you need to wait and how are sentiments about the NRP process going to get weighed into this huddle? OPTN contractor staff added that the guidance is stating that this is critically important that the key personnel is a part of the huddle and that these huddles should involve all key members of the team participating in the NRP procurement. From the Committee's previous meeting, it was discussed that sometimes some of the personnel are not present at the huddles. The guidance document states that these personnel *should* be present.

The member asked that even if the personnel are not going to physically be in the operating room (OR) or participating in the recovery, is the expectation that the accepting transplant program be on the call to discuss the criteria listed in the guidance document.

The Chair confirmed this and pointed out that this was the reasoning why in the guidance document, personnel was clarified as "decision makers". If the program is not physically coming to the NRP OR, how are their sentiments about the acceptance of the organ going to be shared? If there is a group that is recovering for a program, and they are the decision makers, that personnel may have a dual role. There would need to be personnel who would be able to answer the questions outlined in the guidance.

The member followed up by asking if the guidance outlined pertained to kidney programs as well or just heart/lung and liver and intestine? The Chair stated that this would be for the accepting organ. Usually there is not an acceptance because it says accepting transplant program. There usually is not an acceptance for kidney so it was uncertainty that kidneys would be represented other than who would be recovering the kidneys. The member further explained that there are some OPOs that have begun putting an acceptance code in the kidney match run to try to hold programs accountable for accepting.

Another member stated that they are one of those programs that is going into the OR with acceptances for kidneys and added that it would be difficult to get for kidney and liver involvement as well. The member stated that they do a majority of local recovery for their transplant programs and in imagining trying to get the transplant surgeon on a huddle at three in the morning, this would be difficult.

The Committee Chair stated that for NRP, their program holds pre-procurement huddles and have not had a problem getting personnel to attend. Their pre-procurement huddles are meant to be convenient from a timing standpoint.

The member stated that their program holds an internal huddle, but not that NRP has become such a standard practice, it is always the same surgeon and perfusionist, so it is not much of a huddle anymore because it is standard practice.

The member clarified that this guidance should be fine as it would be guiding other programs who may not be as established. The Committee Chair agreed with this and elaborated that based on previous discussions, it was to ensure that all of the elements were included in the guidance document as it would be the framework for an OPO that does not have an NRP program on how to start.

A member voiced agreement in including a huddle in the guidance and voiced their confusion for the accepting transplant program who does not participate in abdominal NRP and now would be reviewing all of these questions. The accepting program who might not be in the OR being on this huddle? The member added that if the accepting program is going to be in the OR, they should participate in the huddle. Committee leadership will review this further to ensure that the guidance accounts for when the accepting transplant program is not present and if additional specification is needed for kidney programs.

Pre-Procurement Huddle (questions): These included bullet points of the specific questions that should be asked during the huddle. The OPTN Contractor summarized that one of the SMEs recommended using the language "highly recommend" for identifying which teams are bringing the equipment needed. Additionally for anesthesia, there was some debate about anesthesia and that not all cases use it, therefore the question specifies that there needs to be confirmation on whether anesthesia would be required or not, and if so, what those requirements would be. There was additional clarification made in the guidance on what the no touch time standoff period is.

A member voiced appreciation as a non-OPO and not very knowledgeable of the language in the document being easy to read and follow through. In the use of the acronyms and following the literary writing to explain what these terms are, it is helpful. In thinking about the audience, specifically donors and donor families, it is important that it is not read scientifically all the time.

Another member commented that for the minimum and maximum NRP pump times, there should be consideration for instances where the team may need to get off circuit. The Committee Chair agreed with this and stated that the minimum and maximum times are anticipated run times. In the first huddle, that's where the discussions are held in determining things such as at what point would the procedure need to be abandoned and go to rapid DCD. OPTN Contractor staff stated that there was a section that outlined including a contingency plan in the huddle discussion. The member agreed with this.

Another member asked that to record and document all of the points outlined in the guidance, will members need to use smart text, checkbox or a lengthy operative note for the final documentation. The OPTN Contractor responded with uncertainty of how these huddles are documented now and added that if there were variation in how these huddles are conducted and documented, the Committee may not want to be prescriptive about this. The Committee was asked for their additional insight on this.

The Committee Chair stated that at their program they document that the huddle occurred and include the date and time of the huddle. A member stated that they use a case note template where they document the huddle and they have certain items within that template that are being discussed during the huddle which is similar to what is included in the guidance document.

Commitment by team members to the NRP procedure: There were no changes made to this section from the Committee's last review and discussion.

Technical Standards for the procedure: The Committee Chair summarized that the mention of predictive modeling was removed based on the Committee's and SME feedback. There was a modification that in removing the statement that donor preparation (prep) was to occur in the OR and instead rephrased it to say: donor prep and draping occur.

A member asked that for the item stating that the provider performing withdrawal of life sustaining therapy (WLST) should be responsible and should not include members of the recovery team or members of the OPO – is that directly from the DCD policy? Usually, there are organ recovery coordinators who record vital signs during the withdrawal.

The Committee Chair confirmed that this was correct and added that the organ recovery coordinators would not be the ones responsible for the withdrawal. The member agreed with this and suggested potentially modifying this statement for clarification purposes. The Committee Chair summarized the question in that OPO staff would be present after the withdrawal happens until the death is pronounced but they are not the staff who are doing the withdrawal. The Committee Chair suggested modifying the sentence to read, "The provider(s) responsible for WLST *procedure* should not include members of the recovery team or members of the OPO". The member agreed with this modification.

The member continued by asked if this was one of those scenarios where "should" may not be the right word since the OPO staff clearly cannot be responsible for the WLST procedure and suggested using the term "must" rather than "should".

Prevention of Cerebral Reperfusion during TA-NRP: The Committee Chair summarized the content of this section which discusses prevention of cerebral reperfusion. There were previous discussions about what this looks like. The SMEs discussed the various methods of assurance, such as venting and double clamping, and therefore agreed the guidance should not be prescriptive on this as it would depend on a surgeon's expertise. The statement was edited to say that there must be a method of assurance in place but not being prescriptive as to what the method should be.

A member asked if there should be a witness or an assigned individual outside of the team who would need to confirm these processes. The Committee Chair explained that the surgeons felt like that was their responsibility to get the procedure done. The Committee Chair also voiced support of staff just asking the question of if there would be someone in the room who could confirm if this is inclusive of confirmation during timeout of if there should be additional language detailing this in the guidance. Committee leadership would review this feedback further.

Prevention of Thoracic and Cerebral Reperfusion during A-NRP: There were no changes made to this section.

Intra-operative Communication: The Committee Chair highlighted the modification made to the language that "the cerebral reperfusion has been rendered infeasible". The modification was made to further clarify that this is not possible and that this is verbally confirmed.

Credentialing Standards/Experience Levels: Based on the Committee's previous discussions, language was included to specify that with experience with A-NRP in isolation does not necessarily confer with experience of TA-NRP and would need to be further reviewed.

A member stated that ACIN just came out a few weeks ago with credentialing for NRP recoveries and asked if it would still be the OPOs confirming in ACIN that the surgeon is approved to do NRP recovery if

the OPO were to perform the NRP recovery. The OPOs would not have to make sure they've done five successful NRP procurements if the credentialing standards are in place, correct?

OPTN Contractor staff stated that the guidance is not prescriptive and would not require the OPTN to monitor anything related to credentialing as it pertains to that process. A note was made to ensure that language was aligned with current practices. OPTN Contractor staff stated that discussions with SMEs concluded that the requirements outlined in the guidance was in alignment with guidance from ASTS but was believed that the ACIN credentialing process in place would be separate from guidance. In wanting to maintain alignment with current practices, guidance, and processes, Committee leadership will look further into the ACIN credentialing guidelines.

Quality Control/Peer Review: There were no changes made to this section.

Data Collection/Documentation: The Committee Chair explained that from discussions with the SME's there were changes made to this section. The OPO Committee is currently working on a data collection proposal for the OPTN Donor Data and Matching System. Since the OPO Committee's data collection is anticipated to take time before it is implemented, this section of the guidance document is to encourage members (especially those who would just be starting NRP at their respective programs) to focused on what is documented on the NRP flowsheet. It was discussed that an NRP flowsheet is fairly standard, but there was feedback about creating some recommendations for what data should be on the NRP flowsheet. There was language included that recommended that the NRP flowsheet be uploaded into the OPTN Donor Data and Matching System as soon as possible. These data points listed in the guidance document are what should be considered for inclusion in that flowsheet.

OPTN Contractor staff added that the guidance document would include some examples of those flowsheets. The flowsheet examples include all of the data points that are listed. The Committee was asked if there was preference in including only the examples, the list of data points, or both.

A member reported that the OPO Committee Workgroup is also working on some data collection specifically around NRP. The member suggested that the Committee cross reference with the OPO Committee to ensure that there is not any overlap in efforts.

OPTN Contractor staff confirmed that during the time that the Committee initially developed the project recommendations, the OPO Committee was made aware of the data points that were being suggested. It was confirmed that a number of the items on the list was in alignment with the OPO Committee's discussions. The OPTN Contractor staff continued to explain that the guidance document would be providing recommendations for members to begin uploading their NRP flowsheets as a way of having documented data available to review within the system rather than adding data fields (which would be deferred to the OPO Committee's efforts). The policy process for data collection proposals can take some time before it is implemented so including this in the guidance document is intended to encouraged a centralized place in uploading this data. The member agreed with this and suggested adding language that the data elements that are being suggested are "not limited to" what is being listed in the guidance document.

Another member voiced preference in including both the listed data points as well as the example of the NRP flowsheets.

A member asked if data would be collected on the methods for prevention of cerebral perfusion – single versus multiple, as well as the location of vessel occlusion during TA-NRP? The Committee Chair pointed out that the last bullet point of that section recommended a data point that provides documentation on the confirmation of occlusion prevention of intercranial flow and documentation of completion of that surgical pause. The Committee Chair stated that if there were suggestions to explain that language, that

modification could be made. A note was made for Committee leadership to review and consider further the inclusion of timing and method of prevention to the list of data points.

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

Next Steps

- Committee leadership will make revisions based on feedback received.
- The Committee will review the draft guidance document and provide any additional feedback for consideration.

Upcoming Meetings

- Thursday, February 27, 2025 (Teleconference)

Attendance

- **Committee Members**
  - Kim Koontz
  - Amanda Bailey
  - Anja DiCesaro
  - Annemarie Lucas
  - Bridget Dewees
  - Elizabeth Shipman
  - Jillian Wojtowicz
  - Kaitlyn Fitzgerald
  - Megan Roberts
  - Norihisa Shigemura
  - Sarah Koohmaraie
  - Mony Fraer
- **SRTR Staff**
  - N/A
- **HRSA Staff**
  - N/A
- **UNOS Staff**
  - Joann White
  - Betsy Gans
  - Kaitlin Swanner
  - Laura Schmitt
  - Niyati Upadhyay
  - Susan Tlusty