OPTN ORGANPROCUREMENTAND TRANSPLANTATION NETWORK

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October 8, 2024

Dr. Suma Nair
Associate Administrator
Health Systems Bureau
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

VIA ELECTRONIC MAIL

Dear Associate Administrator Nair:

Thank you for the opportunity to provide HRSA with additional information about the Organ Procurement and Transplantation Network (OPTN)'s current efforts related to the practice of recovering deceased donor organs using normothermic regional perfusion (NRP) techniques. As HRSA is aware, the OPTN has been considering the ethical and practical issues related to NRP for the last couple of years. In addition to the requested information, which we have included below in Appendix A and made available to HRSA via a secure file sharing site, I will provide you with background on the OPTN's approach to this topic since 2022.

As HRSA notes in its letter, the technique of using normothermic regional perfusion (NRP) for donation after circulatory death (DCD) organ donor recoveries has increased. The OPTN has discussed NRP many times and is generally supportive of innovative techniques that may increase the number of donated organs. Since NRP is a type of DCD donation, it is currently governed by OPTN Policy 2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols. This policy requires organ procurement organizations (OPOs) and transplant hospitals/donor hospitals to have agreements and protocols to define roles and responsibilities for evaluation and management of potential DCD donors, organ recovery and organ placement. Any potential violations of this or any policy or bylaw have been and will continue to be thoroughly investigated by the OPTN Membership & Professional Standards Committee (MPSC) and adjudicated appropriately under the auspices of confidential medical peer review. Moreover, after seeing a rise in NRP cases, the MPSC communicated with the transplant community about this topic in January 2023, reminding OPOs and transplant hospitals about the OPTN's policy.

Recognizing that the existing OPTN policy on DCD recoveries does not contain provisions specific to NRP recoveries, and because it is imperative that the OPTN's decision-making be grounded in sound evidence, in December 2022, the OPTN Board of Directors (BOD) approved the collection of additional data to understand whether deceased donors' organs were recovered using an NRP technique. These data have not yet been collected, because the proposed data collection is in a package awaiting submission by HRSA to the Office of Management and Budget (OMB) for approval for new data collection. In the meantime, on September 26, 2024, the OPTN Executive Committee approved a new

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project for the OPO Committee to recommend even more granular data collection regarding NRP recoveries.

Additionally, in January 2024 the OPTN published a white paper considering the ethical implications of NRP, which concludes in part that "consistent and transparent protocols, including adequate informed decision making with patients (pre-mortem) and of families approached about donation, are necessary pre-conditions for any ethical pursuit of NRP." Building upon the recommendation from this white paper, as OPTN President I recently led a discussion of the OPTN Executive Committee about NRP, and we determined it is imperative that the OPTN develop consistent and transparent protocols that all OPOs and transplant hospitals engaged in NRP recoveries must follow. Otherwise, there is a risk that the lack of standardized protocols will begin to cause distrust and could negatively impact people's willingness to agree to organ donation. Therefore, on September 26, 2024 we took the following action: The OPTN Operations & Safety Committee is charged with establishing requirements for standardized practice in the use of NRP in organ procurement by both OPOs and transplant hospitals. The committee will share a progress report with the Board of Directors no later than November 15, 2024.

The OPTN is, of course, not the only entity that oversees organ donation. In addition to all the OPTN policies detailed above and below, the Centers for Medicare & Medicaid Services (CMS) certify and oversee OPOs and establish conditions for coverage for all OPOs. Furthermore, declaring death and recovering organs is also governed by each state's individual laws. While many have adopted the recommended uniform laws on these topics, it is important to understand each state's specific adopted version of the law to account for certain nuanced differences from state to state.

Finally, it should be emphasized that it is not just OPOs engaged in the practice of NRP. In fact, often the protocols are developed and executed by or with transplant hospitals and donor hospitals. Therefore, after discussion with OPTN leaders, and with HRSA's approval, we are also requiring OPTN contractor staff to request similar information from transplant hospitals as was requested from OPOs. Information submitted by transplant hospitals to the OPTN will be uploaded for HRSA's review on a rolling basis as it is received, and in any event the deadline for transplant hospitals to submit responsive information is October 18, 2024.

Thank you again for your careful consideration of this important topic.

Sincerely,

/ Rich Formica /

Richard N. Formica, Jr., MD
President, OPTN Board of Directors

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APPENDIX A

1. **A complete description and timeline of all MPSC and/or Operations and Safety Committee activities related to the potential adverse events communicated by the incident reporter occurring at OPO member- including the dates of complaint, all committee discussions, and all data and documents collected in the evaluation, investigation, and/or adjudication of the complaint. Please also include all correspondence between the OPTN contractor, MPSC, and/or Operations and Safety Committees, and- regarding the complaint.**

Because potential adverse events **are managed** by **the MPSC, and** the **intake,** investigation, and disposition are all evaluated pursuant to confidential medical peer review processes, all documents responsive to this **request** will be uploaded into a secure file sharing **site** which **HRSA** will be able to **access.** Of note, any documents that were provided by the member are already actually or constructively in **HRSA's** possession through HRSA's participation on the MPSC and **MPSC** leadership activities. We are providing a courtesy copy, but we are not producing any materials that HRSA does not already possess. This statement is true for any responsive materials produced in response to your letter.

2. **For each OPTN OPO member:**
    a. The member's policy regarding the use of NRP within their Donation Service Area.
    b. The current list of third-party vendors with which the OPTN OPO member contracts or formerly contracted for NRP.
    c. The member's training requirements, licensure requirements, and/or procedures around the use of NRP in any of the following clinical settings: donor hospitals, **privately held OPO surgical facilities, or OPO-operated, hospital-based surgical units.**

The OPTN does not collect these documents in the normal course of operations. The OPTN is permitted to request these documents under the OPTN Bylaws, and as a result of this critical comment staff for the OPTN Contractor are reaching out to every OPO to obtain documents responsive to this request. As I noted in my email to you on Friday, October 4, this is an extensive request and OPOs needed more time to gather their documentation for submission, so I have advised that they have until 9 a.m. on October 11 to submit their documentation. The OPTN Contractor will upload the documentation from OPOs as received, on a rolling basis. These too will beuploaded to a secure file sharing site, as these documents are also being collected under the auspices of confidential medical peer review.

3. All OPTN **Bylaw** and Policy requirements related to use, monitoring, data reporting, and clinical setting for NRP in the care of potential organ donor patients.

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The following policies outline OPTN member responsibilities for organ recovery, including policies specific to donation after circulatory death (DCD), which would apply to organ recoveries using NRP techniques:

- *Policy 2.2: OPO Responsibilities*
  - 2.2(5) – Host OPO must verify that death is pronounced according to applicable laws
  - 2.2(14)(d) – Host OPO must provide the OPTN with required deceased donor information including "death pronouncement source documentation."
- *Policy 2.11: Required Deceased Donor Information*
  - 2.11(10) – Host OPO must report to the OPTN all organ anatomy and recovery information for each deceased donor
- *Policy 2.14.C: Organ Procurement Procedures*
  - 2.14.C(4) – Host OPO must use standard surgical techniques in a sterile environment
- *Policy 2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*
  - "Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statutes or regulations."
  - "These policies will help OPOs and transplant hospitals develop necessary DCD protocols. These set the minimum requirements for DCD recovery but do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs, transplants hospitals, and donor hospitals."
  - *2.15.B: Protocols*
    OPOs and donor hospitals must establish protocols that define the roles and responsibilities for the evaluation and management of potential DCD donors, organ recovery, and organ placement in compliance with OPTN Policy.
  - *2.15.F: Withdrawal of Life Sustaining Medical Treatment or Support*
    Prior to the donor hospital withdrawing life-sustaining medical treatment or ventilated support, the OPO is required to conduct a timeout to confirm:
    1. The patient's identification.
    2. The process for withdrawing life-sustaining treatment or ventilated support.
    3. Roles and responsibilities of the primary patient care team, the OPO team, and the organ recovery team.
    4. The hospital's plan for continued patient care if the patient does not become a donor, and appropriate communication with the next of kin.

    No recovery personnel (surgeons and other recovery practitioners) may be present for the withdrawal of life-sustaining medical treatment or ventilated support. No member of the organ recovery team or OPO staff may guide or administer palliative care or declare death.
  - *2.15.G: Pronouncement of Death*

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The donor hospital healthcare team member who declares the death of the potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. Death is declared in accordance with hospital policy and applicable state and local statutes or regulation.

- *2.15.H: Organ Recovery*
  Organ recovery will only proceed after circulatory death is determined, inclusive of a predetermined waiting period of circulatory cessation to ensure no auto-resuscitation occurs.

4. All OPTN Bylaw and Policy requirements related to the training for OPO procurement and surgical staff, including contracted transplant center-affiliated surgeons, third-party procurement contractors, and OPO surgical teams, using NRP in the care of potential organ donor patients.

Policies

- See response to previous question.

Bylaws

- *Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)*
  - *B.6: Additional Requirements*
    H. Donation after Circulatory Death (DCD) Protocols
    Each OPO must develop and comply with protocols to facilitate the recovery of organs from DCD donors. OPO DCD recovery protocols must address the requirements as described in Policy 2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols. These protocols must be made available to the OPTN Contractor on request.
- *Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs*
  - *D.12 Additional Transplant Program Requirements*
    E. Donation after Circulatory Death (DCD) Protocols
    Each transplant hospital must develop and comply with protocols to facilitate the recovery of organs from DCD donors. Transplant hospital DCD recovery protocols must address the requirements as described in Policy 2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols.

Data collection

- In December 2022, the OPTN Board of Directors approved a proposal that added DCD clinical data collection, including the following NRP data elements[1]:
  - NRP recovery, yes/no

[1] https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/enhancements-to-optn-donor-data-and-matching-system-clinical-data-collection/

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    - Initiation of NRP, date/time
- As of October 3, 2024, these data elements are awaiting OMB approval and therefore have not yet been implemented.

5. **The process that the OPTN uses to review and adjudicate reports made to the OPTN regarding both use of NRP and/or adverse events involving donor patients who were placed on NRP, including:**
    a. **The OPTN committees that receive information about the nature and number of patients placed on NRP and/or NRP adverse event reports.**
    b. **Which OPTN committees and/or OPTN staff/teams that review reports of patients placed on NRP and/or NRP adverse event reports**
        i. **For each committee, please include the cadence at which the committee receives reports and any associated data analysis generated regarding patients placed on NRP and/or NRP adverse event reports, individually or in aggregate.**
        ii. **For each OPTN staff/teams, please include the cadence at which the staff/teams receive reports and any data analysis generated regarding patients placed on NRP and/or NRP adverse event reports, individually or in aggregate.**

The OPTN does not have a specific, NRP-dedicated process for receiving, reviewing, or adjudicating reports regarding NRP use or adverse events involving NRP-related donors. Contractor staff supporting the OPTN reviews and investigates NRP-related reports using the standard intake and investigative process used for all other types of reports of potential patient safety issues and policy noncompliance. A description of this process is posted on the OPTN website, and the relevant section, "Patient Safety and Non-routine Compliance Reviews" begins on page 11.

The OPTN MPSC adjudicates any reports of OPTN Policy noncompliance or patient safety issues related to NRP. The MPSC adjudicates NRP-related reports using the same methods they use to review all other reports of potential patient safety issues and policy noncompliance. Neither staff investigating these issues nor the MPSC use an NRP-specific review or adjudication process.

The MPSC is the only committee that receives information about adverse events involving donor recoveries that utilized or attempted to utilize NRP for those recoveries. There is no OPTN committee that receives reports of the nature and number of all donors whose recovery utilized NRP. Staff who review these reports are Patient Safety staff and Compliance Operations staff.

- There is no regular cadence at which the MPSC receives the investigation summary of NRP-related events. When Patient Safety staff complete an investigation, they compile the investigation packet and send it to Compliance Operations staff, who will prepare the case and send it for MPSC review. This is done on a rolling basis, as the investigations are completed.
- The MPSC reviews individual adverse event reports. They receive aggregate data on all patient safety reports monthly, which includes NRP-related cases, but they do not receive NRP-specific aggregate data.

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- There is no regular cadence at which staff receive reports of NRP-related adverse events. Reporting NRP-related adverse events is voluntary, and staff receive them only when someone makes a report, which can happen at any time.
- Staff do not receive regular data on patients placed on NRP or adverse events in aggregate.

6. **All data collected by or reported to the OPTN since 2021 that tracks or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding patients placed on NRP and/or NRP adverse event reports by OPTN member organization.**

This information will be provided to HRSA by 5 p.m. on October 11, 2024. The OPTN Contractor will upload the data to the secure file sharing site.

7. **All data reporting generated for the OPTN since 2021 that tracks or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding patients placed on NRP and/or NRP adverse event reports at the OPTN system level.**

This information will be provided to HRSA by 5 p.m. on October 11, 2024. The OPTN Contractor will upload the data to the secure file sharing site.