Ensuring Safety and Reliability in Normothermic Regional Perfusion Protocols — A Message to the OPTN Community

Nov. 21, 2025

Dear OPTN Members,

The OPTN, in collaboration with HRSA, is issuing this message to highlight a critical safety concern in normothermic regional perfusion (NRP) procedures, specifically the potential for unintended reperfusion of the brain and brainstem after initiation of NRP.

Unintended reperfusion may occur as a result of unrecognized collateral circulation, aberrant anatomy, or clamp failure. The OPTN has received verified reports of such events. Though extremely rare, these events call for heightened vigilance and standardized practice across all organizations involved in NRP. The OPTN is developing new policy requirements and associated data collection procedures to further improve system safety. Communication regarding these efforts will be forthcoming.

In the interim, to reinforce patient safety, improve trust in organ donation and procurement, and increase consistency in practice, OPTN members involved in NRP should undertake immediate review of their own policies to address these recommendations.

1. **In abdominal NRP (A-NRP), the aorta should be occluded above the level of celiac origin, either below or immediately above the diaphragm, AND the proximal aorta should be transected cephalad to the occlusion and allowed to drain to the atmosphere prior to the initiation of perfusion.**

Appropriate approaches to aortic occlusion may include the application of a vascular clamp or an intra-aortic balloon. Regardless of the occlusion technique, transection and drainage of the proximal aorta is required prior to initiating perfusion. The approach to aortic occlusion and the time the proximal aorta is transected should be documented in the OPO donor record.

2. **In thoraco-abdominal NRP (TA-NRP), the vessels arising from the aortic arch (the brachiocephalic, left common carotid, and left subclavian arteries) should be individually occluded near their origin AND each artery should be transected and allowed to drain to the atmosphere prior to the initiation of perfusion.**

Appropriate approaches to occlusion of individual aortic arch vessels may include application of a vascular clamp, ligation, or a vascular stapler. Regardless of technique to achieve proximal occlusion, individual transection and drainage of the cephalad ends of each of the transected arteries is required prior to initiation of perfusion. Occlusion of all vessels can precede transection of all vessels. The surgeon should be familiar with variations in the anatomy of aortic arch vessels and appropriately manage any variations. Occlusion of multiple vessels with a single clamp is not appropriate given the risk of a single clamp not

completely securing all vessels or subsequent clamp dislodgement. The individual aortic arch vessels transected should be documented in the OPO donor record. In addition, the time the last aortic arch vessel is being transected should be documented in the OPO donor record.

3. **Ensure that all stakeholders involved in the NRP procurement process (OPO staff, hospital staff, transplant center staff, and third-party procurement and preservation staff) are aware of the need to prevent unintended cerebral reperfusion, review the methods being used to avoid cerebral reperfusion, and have a coordinated plan to address and manage concerns that may arise.**

The plan for securing and transecting appropriate vessels should be reviewed with all members of the recovery team as part of the pre-recovery time out. Additionally, the team should review the plan for managing unplanned scenarios, including inability to achieve proximal vessel occlusion, sustained back bleeding from transected vessels, and clamp dislodgement. The contingency plan may include rapid conversion to perfusion with cold preservation solutions, occlusion of the abdominal aorta in the case of TA-NRP, rapid recovery, etc.

We request that all OPTN member organizations share this information with all their team members and conduct baseline education sessions with all team members involved in NRP to ensure adherence to these recommendations. All OPTN member organizations involved in NRP are responsible for the conduct of their representatives, including any subcontractors (e.g. third-party vendors).

4. **Report all observations of unintended cerebral reperfusion via the OPTN Patient Safety Reporting Portal.**

Reporting incidents enables learning, identifies systemic risks, and protects patients, providers, and the public's trust. When reporting an unintended reperfusion event, include in your report: the timeline (time of death declaration, observation period, incident of unintended reperfusion), monitoring modalities used, clinical signs observed, and actions taken. In addition, OPTN members are encouraged to share learnings (redacted as appropriate) and best practices with each other so the community can benefit from increased knowledge and consistency in practice.

Background

NRP has been used for several years in the United States and in other countries. In some cases, it may provide the only means to recover certain transplantable organs and honor the intent of donor patients or donor patient families.

NRP is used only in potential donor patients who are being evaluated for donation after circulatory death (DCD). After the potential donor patient's treatment team has declared death due to loss of circulatory and respiratory function, and after an observation period is

completed, the organ recovery team uses NRP to provide in situ perfusion to a localized area of the body until organs can be recovered. There are two different NRP procedures. In abdominal NRP (A-NRP), perfusion is limited to abdominal organs; neither the heart nor lungs are perfused. In thoraco-abdominal NRP (TA-NRP), the thoracic and abdominal organs are perfused. In both modalities, the procedures are performed in a manner that prevents restoration of perfusion of the brain.

The OPTN has policy requirements for its members regarding DCD procedures, most of which are contained in *OPTN Policy 2.15* (*Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*). However, to date, there is no national set of requirements or standards addressing the specific practice of NRP. Many OPOs and transplant hospitals have developed their own protocols, some of which are further customized to the donor hospital involved in the donation process.

Some clinicians and experts from various disciplines, as well as members of the public, have expressed questions or concerns regarding some aspects of NRP. A particular focus of discussion has been whether and to what extent reperfusion could restore any cerebral or nervous system function in potential donors who have been declared dead, and the measures taken by procuring teams to ensure the absence of any cerebral reperfusion during the NRP procedure. Transecting and draining vessels cephalad to the region of perfusion to the atmosphere is currently the most failsafe approach to ensuring no cerebral reperfusion.

We appreciate the diligence and professionalism of all OPTN members in advancing lifesaving organ donation, procurement, and transplantation. As part of that commitment, we must ensure the highest standards of patient safety, ethical integrity, and transparency remain at the forefront of all we do.

Thank you for your cooperation and continued dedication to safe, reliable organ donation and procurement practice.

Sincerely,

John C. Magee, MD
President, OPTN Board of Directors