The American Society of Transplant Surgeons Consensus Statement on Normothermic Regional Perfusion

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Abstract. On June 3, 2023, the American Society of Transplant Surgeons convened a meeting in San Diego, California to (1) develop a consensus statement with supporting data on the ethical tenets of thoracoabdominal normothermic regional perfusion (NRP) and abdominal NRP; (2) provide guidelines for the standards of practice that should govern thoracoabdominal NRP and abdominal NRP; and (3) develop and implement a central database for the collection of NRP donor and recipient data in the United States. National and international leaders in the fields of neuroscience, transplantation, critical care, NRP, Organ Procurement Organizations, transplant centers, and donor families participated. The conference was designed to focus on the controversial issues of neurological flow and function in donation after circulatory death donors during NRP and propose technical standards necessary to ensure that this procedure is performed safely and effectively. This article discusses major topics and conclusions addressed at the meeting.

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BACKGROUND

On June 3, 2023, the American Society of Transplant Surgeons (ASTS) convened a meeting in San Diego, California, to (1) develop a consensus statement with supporting data on the ethical tenets of thoracoabdominal normothermic regional perfusion (TA-NRP) and abdominal NRP (A-NRP); (2) provide guidelines for the standards of practice that should govern TA-NRP and A-NRP; and (3) develop and implement a central database for the collection of NRP donor and recipient data in the United States. National and international leaders in the fields of neuroscience, transplantation, critical care, and NRP, along with representatives from Organ Procurement Organizations, transplant centers, and donor families participated. This article discusses the major topics addressed at the meeting (**Tables 1 and 2**).

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TABLE 1.

Perspectives on normothermic regional perfusion (NRP), including US legal and ethical considerations, and national transplant society positions

Topic	Statement
Utility of NRP	• NRP is superior to standard rapid recovery DCD donation in heart, liver, and kidney recipient outcomes • Procurements after TA-NRP have higher abdominal organ utilization rates than standard rapid recovery cardiac DCD donation
US legal framework	NRP is legally acceptable if: • The common law standard for determination of death is used, which says that cardiopulmonary death is defined as the absence of spontaneous respiratory and cardiac function • Agreement that in situ perfusion with mechanical ventilation does not constitute spontaneous respiratory and cardiac function when the heart restarts • Is consistent with the donative intent of the first person or surrogate authorization for organ donation
Ethical considerations	To adhere to the dead donor rule, NRP must be consistent with the conceptualization of death, which is if the following are true: • NRP follows the standard DCD process for the declaration of death, observation period to ensure the absence of autoresuscitation, and confirmation of death before initiating the procedure • NRP perfuses only the organs intended for transplantation • Organ perfusion does not constitute a resuscitative procedure and is not consistent with restoration of life-defining, whole-body circulation If the NRP donor is dead per the above-mentioned criteria, then it must not be harmful to the decedent. It achieves this benchmark if: • There is no meaningful flow to the brain, representing no possibility of neuronal perfusion or recovery If NRP is ethically acceptable and results in higher organ utilization rates and better recipient outcomes, then it would be considered ethically obligatory based on the principles of respect for autonomy and beneficence
Neurophysiologic considerations	• Flow in a stroke core is 4–8 mL/100 g/min. Flow to the brain in the TA-NRP procedure is 3.9 mL/100 g/min, which is incompatible with neuronal activity • Transcranial Doppler studies of 2 TA-NRP donors are consistent with the absence of flow during TA-NRP • Intracerebral blood pressure studies of 8 A-NRP and 2 TA-NRP donors are consistent with the absence of flow during NRP procedures
Society Statements	ASTS Supports NRP as an ethically sound organ procurement modality and recommends: • Establishment of standards for NRP organ recovery in the United States • Development of a national database to monitor NRP outcomes and the conduct of NRP procurement procedures AST supports NRP within the confines of the UDDA • Endorses further research on donor family information needs and communication strategies

AST, American Society of Transplantation; ASTS, American Society of Transplant Surgeons; DCD, donation after circulatory death; NRP, normothermic regional perfusion; TA-NRP, thoracoabdominal normothermic regional perfusion; UDDA, Uniform Determination of Death Act.

SETTING THE STAGE: THE IMPACT OF ORGAN DONATION AFTER CIRCULATORY DEATH (ELIZABETH POMFRET)

Organ donation after circulatory death (DCD) has increased in the United States by approximately 15% to 30% per annum during the past 3 y and remained the area with the highest growth potential. NRP is a technique that involves rapid cannulation of blood vessels after death is declared, followed by perfusion to the organs that will be used for transplantation. NRP uses in situ perfusion with oxygenated blood using an extracorporeal membrane oxygenation circuit or cardiopulmonary bypass circuit.[1] In 2020, Vanderbilt University and New York University became the first US programs to use NRP for DCD heart donors.[1,2] Reports of heart, liver, and kidney transplant recipient outcomes in the United States showed excellent early results.[1,3-5] Despite the promising clinical outcomes for recipients of NRP donors, ethical uncertainty surrounding the procedure has been voiced by several groups.[6,7]

UNITED KINGDOM PERSPECTIVE ON NRP (DR CHRISTOPHER WATSON)

Both Spain and the United Kingdom have used NRP for decades.[8-10] The first UK TA-NRP case occurred on November 5, 2006, which was followed by several years of funding and research but was paused because of ethical concerns about possible brain perfusion through collateral flow. In Spain, the use of TA-NRP for heart transplantation has continued with a protocol requiring mandatory ligation of the 3 aortic arch vessels and venting of the cephalad ends to the atmosphere before the initiation of NRP.[11] The first UK A-NRP case was performed in 2010, and the first liver transplant from an NRP donor in the United Kingdom was performed in 2011. By 2018, 43 NRP liver transplants had been performed in the United Kingdom, with improved early graft function, graft survival, and recipient renal function compared with liver transplant recipients from rapid recovery DCD donors.[10] Moreover, no ischemic cholangiopathy was associated with NRP, whereas it was observed in 27% with rapid recovery and static cold storage. Because of this early success, A-NRP has been widely adopted in the United Kingdom and a national program has been developed for mentoring, protocolization of technique, and review of outcomes. The UK protocol for A-NRP uses femoral vascular cannulation or intra-abdominal aorta and vena cava cannulation with occlusion of the thoracic aorta and venting of the ascending aorta to air. A standard NRP data collection

TABLE 2.

Future directions in NRP

Requiring assessment	Statement of needs
Standardization of NRP procedures	The following elements of the NRP process for both TA- and A-NRP need to be systematically implemented across the United States to standardize the procedure: • Communication: prerecovery phone discussion, on-site preprocedure team briefing, intraoperative time out to ensure exclusion of cerebral circulation • •Case event recording: time of death, time of incision, start of agonal time (with agreement on the criteria for agonal time), time of NRP initiation. • Technical standards: clamping or venting location and confirmation techniques, cannulation techniques • Certification of procurement surgeons who perform NRP procedures
Qualitative research	The following avenues of qualitative research need to be developed for further assessment of perceptions and experiences with NRP DCD organ donation: • Public perceptions of NRP donation procedures • Donor family experiences and perceptions of NRP donation • Donor hospital staff experiences and perceptions of NRP donation
Quantitative research	The following quantitative research topics need to be addressed to further understand the impact of NRP organ donation procedures • Recipient outcomes for all solid organ transplant types • Donor characteristics and functional warm ischemic times associated with acceptable and unacceptable recipient outcomes • Organ utilization rates were standard rapid recovery with and without ex situ machine perfusion

A-NRP, abdominal normothermic regional perfusion; NRP, normothermic regional perfusion; TA-NRP, thoracoabdominal normothermic regional perfusion.

sheet is used by all centers and made available to receiving centers for review.[12]

Because TA-NRP is on pause in the United Kingdom, techniques have been developed for the direct procurement and perfusion (DPP) of thoracic organs using ex situ machine perfusion.[13,14] Although thoracic DPP is possible in combination with A-NRP, the competing needs of the abdominal and thoracic teams and the different technologies that are not complementary make widespread utilization of this complex procurement procedure challenging. Because TA-NRP can perfuse abdominal and thoracic organs simultaneously with a single machine and a unified procurement technique, it has the greatest potential for more efficient utilization of all organs for transplantation.[4] As a result, there are efforts underway in the United Kingdom to bring TA-NRP back into practice following legal and ethical guidelines.

US LEGAL CONSIDERATIONS IN NRP ORGAN PROCUREMENT (BRADLEY ADAMS)

The legal parameters that govern the determination of death are central to debates about NRP organ procurement. Notably, until the 1960s, death was determined solely by cardiopulmonary criteria. This changed with the introduction of new technologies including mechanical ventilation and defibrillation. In 1967, the Ad Hoc Committee of Harvard introduced the concept of death by neurologic criteria as defined by irreversible coma,[15] and this became a legal construct of death in the United States in 1968. In 1981, the Uniform Determination of Death Act (UDDA)[16] was introduced to develop consistent criteria for death throughout the United States. According to the UDDA, either set of criteria for the determination of death (neurologic or cardiopulmonary) is sufficient for both the declaration of death and proceeding with organ procurement.

Much of the legal debate around NRP centers was on the term *irreversibility*, which is used for both the neurologic and cardiopulmonary determinations of death under the UDDA. Irreversibility is, in this context, defined as cessation of function that cannot be restarted. However, given the advancement of technology, it is now possible to restore or replace organ function with aggressive intervention. Therefore, the concept of irreversible has been replaced with the concept of *permanent*, which means that once function has ceased, it cannot resume spontaneously.

From a legal standpoint, there is debate about whether NRP procurement techniques meet the criteria for the determination of death. The UDDA codifies the legal definition of death by either circulatory/respiratory or neurologic criteria and specifies that "the determination of death must be made in accordance with accepted medical standards." Notably, prefatory notes to the UDDA state that "the common law standard for determining death is the cessation of all vital functions, traditionally demonstrated by an absence of spontaneous respiratory and cardiac functions."[16] The central legal question that TA-NRP highlights is if the perfusion of organs, including the heart which restarts, negates the circulatory determination of death. The exact meaning of irreversibility is central to the answer to this question. In terms of common law, spontaneity was part of the intended definition of irreversibility. If that is the case, many have argued that permanence is a better term than irreversible because permanence means that spontaneous circulatory and respiratory functions have stopped and will not be restarted.[17] Having an exact time of death is essential not only for the purposes of organ donation but also for the transfer of property rights, estate taxation, and the determination of when healthcare decisions can be made. Based on current US law, combining accepted medical standards and intent regarding withdraw life-sustaining interventions, the irreversible cessation of circulatory and respiratory functions can be consistent with TA-NRP techniques if we agree that the common law interpretation of the absence

of spontaneous respiratory and circulatory functions is met and that the intent of the process (to allow for death to happen and not to resuscitate the person after death has been declared) leads to permanent cessation of circulatory and respiratory function to the entire body, including the brain. In other words, if regional perfusion does not resume spontaneous, full body, circulatory, and respiratory functions, then TA-NRP meets legal standards for the determination of death. Opening the UDDA to revision would likely result in more restrictive interpretations of death rather than more clarity in the terminology. Fortunately, the Uniform Law Commission leadership recently decided to pause the revision of the UDDA indefinitely (Judge Samuel Thumma, Chair of the Uniform Law Commission's Determination of Death Committee, e-mail communication, September 22, 2023).

ETHICAL CONSIDERATIONS IN NRP ORGAN PROCUREMENT (BRENDAN PARENT AND ANJI WALL)

From an ethical standpoint, the first objection to NRP donation is that the procedure negates circulatory death ethically, even if it does not violate legal norms, because it "restarts circulation." As noted previously, NRP does not meet the strict irreversibility standard that states that circulatory and respiratory functions have stopped and *cannot* be restarted because most other organ functions can be restarted with or replaced by mechanical assistance. NRP does meet the permanence standard that states circulatory and respiratory functions have stopped and cannot resume spontaneously. NRP does not restore circulatory and respiratory functions but rather provides in situ perfusion to the organs intended for transplantation. Because the DCD donor is observed for at least 5 min of no cardiopulmonary activity before the confirmation of death to ensure no autoresuscitation, the donor is dead at the initiation of the NRP procedure.[18] Simply restoring organ function with mechanical assistance does not restore life-defining, spontaneous circulatory and respiratory function.

A second ethical objection to NRP is that the ligation of blood vessels to the brain before initiation of NRP *causes* the death of the donor and, therefore, makes NRP inconsistent with the Dead Donor Rule, which states that organ procurement must not cause death. In response to this objection, we must be clear on the NRP procedure and the terminology used to describe it. The donor has been declared dead by circulatory criteria. The NRP procedure that follows entails regional perfusion and preservation of the organs intended for transplantation. NRP does not result in the reanimation or resuscitation of the person because it limits perfusion to the organs being assessed for transplantation. Very clearly, ligation of blood vessels to the brain cannot cause death because the donor is already dead. Another ethical objection to NRP is that there may be a risk that the donor could have an "experience" of donation via NRP (eg, a level of conscious awareness). This must be addressed with research on brain function during NRP.

NEUROPHYSIOLOGY AND THE NRP DONOR (AJMAL ZEMMER, EDUARDO MIÑAMBRES, AND JENNIFER FRONTERA)

One central focus of this meeting was on the neurophysiology of brain blood flow and how this can be interpreted in NRP DCD organ donation. A concern with NRP DCD donation is that there is not sufficient evidence to demonstrate that clamping is adequate to maintain the state of absence of brain function through minimization of flow. From a neurological perspective, brain blood flow has been extensively studied in terms of normal function and stroke physiology.[19-21] Normal brain blood flow is approximately 50 mL/100 g/min, or 800 mL/min, which is 15% to 20% of the body's cardiac output. Electrical activity ceases at a blood flow at ≤16 to 18 mL/100 g/min, membrane integrity is disrupted at ≤10 to 12 mL/100 g/min, and a stroke core has a flow of 4 to 8 mL/100 g/min.[20,21] The oft-cited article by Manera et al (2019)[22] that demonstrated collateral blood flow to the brain after clamping in a TA-NRP donor estimated the flow rate to be 3.9 mL/100 mg/min, which is below the flow rate compatible with life, or more specifically, with a resumption of neuronal activity.

One area of research in need of clarification on the ethical objection to NRP that there could be sufficient flow to the brain after clamping the brachiocephlic vessels to result in neuronal function is real-time flow studies in NRP donors. In a study of TA-NRP donors at New York University, transcranial Doppler of the anterior and posterior circulation was conducted before the withdrawal of life-sustaining treatment and after TA-NRP initiation.[23] In this protocol, after the sternotomy, the brachiocephalic, left common carotid, and left subclavian arteries were ligated before initiating TA-NRP. In the 2 cases for which this study was conducted, neither donor had flow evident by transcranial Doppler after the initiation of TA-NRP, and both had no brainstem reflexes, no spontaneous respiratory effort, and no spontaneous movement, confirming the absence of brain function. A second study on brain blood flow in NRP donors from University Hospital Marqués de Valdecilla used intracerebral arterial blood pressure (ICBP) monitoring during NRP procedures.[24] This study included 8 A-NRP donors and 2 TA-NRP donors. All A-NRP donors had normalization of abdominal aortic blood pressure, whereas ICBP and thoracic aortic blood pressure remained static at the level observed after circulatory arrest. In the TA-NRP donors, the blood pressure in the thoracic and abdominal aorta normalized on NRP, whereas ICBP remained static at the level observed after circulatory arrest.

REFRAMING THE ETHICAL ASSESSMENT OF DCD DONATION (ANJI WALL)

Beyond asking whether NRP meets the baseline ethical standards for the acceptability of DCD organ donation, we should also consider a broader conceptualization of the ethical framework for DCD donation. Historically, concerns about harm to the donor, such as the potential to hasten death and conflict with the Dead Donor Rule, have been the driving forces for the assessment of the acceptability of DCD organ donation.[7] In the 1997 report on Non–Heart-Beating Organ Transplantation, the Institute of Medicine named avoiding harm or

potential harm to the donor patient as the first underlying ethical consideration for DCD donation.[25] The other ethical considerations included supporting donor and family choice and avoiding conflicts of interest between organ procurement and donor patient care. The Institute of Medicine did not present extensive empirical data in their report but did interview 2 families who wanted to pursue DCD donation and were unable because of policies that would not allow it. The report notes that "in both cases, the loss of the option to donate organs was a source of deep regret to the families and compounded their feelings of loss."[25] This concept has been termed the "harm of no donation." If a family authorizes and intends for organ donation to occur and it does not, this produces a second hit to an already tragic situation because one good thing that could have resulted from death does not happen.[26]

Three donor family narratives were presented in the meeting that helped contextualize the personal meaning of organ donation for families of decedents.[27,28] All 3 family representatives described the immense pain of losing a loved one and how organ donation positively impacted their grieving process. In-person donor family members had children who were donors after the neurologic declaration of death. When asked if they would have been accepting of DCD, and specifically NRP DCD donation, both were concerned that providing too much complex information to donor families would be overwhelming and that they would not have been able to process the information in their own circumstances. They would have proceeded with donation based on their perception that this is what their loved one would have wanted and that the procurement team would only perform medically and ethically acceptable procedures.

Based on these discussions and centering on the family experiences with organ donation, we suggest that the obligation to respect the donation decision should be the ethical lens through which DCD processes and protocols are assessed. If we stay within the ethical guardrails of DCD donation by avoiding harm to the potential donor, then we should strive to make donation possible. Organ recovery procedures that increase the opportunity for organ utilization are associated with better recipient outcomes and are not just ethically acceptable but ethically obligatory.

CRITICAL CARE PERSPECTIVE (LEWIS KAPLAN AND CHERYLEE CHANG)

The critical care perspective on NRP DCD donation focuses on how this procedure integrates into end-of-life care. The concept of goal-concordant care is central to end-of-life decision-making in the intensive care unit and means that the care provided has a reasonable chance of achieving the goal of the treatment. DCD organ donation within goal-concordant care for a nonsurvivable illness or injury when the decision has been made to transition to comfort care and organ donation is an option. NRP is consistent with goal-concordant care when a decision has been made to transition to comfort care because it allows for donation to occur after death, just as with standard DCD donation.

THE POSITION OF ASTS AND AMERICAN SOCIETY OF TRANSPLANTATION ON NRP (ELIZABETH POMFRET, WILLIAM CHAPMAN, DEEPALI KUMAR, AND JOSHUA LEVITSKY)

The ASTS recognizes that there are ethical considerations regarding NRP procedures but feels strongly that NRP saves lives and offers an ethically sound donation modality that does not violate essential moral, philosophical, or bioethical principles. NRP must be implemented in a way that maximizes the number of patient life years saved and follows the highest ethical standards. To do this, several committees will be formed to provide guidelines for the standard of care and ethical boundaries for the conduct of TA- and A-NRP.

The American Society of Transplantation supports the use of NRP.[29] From a scientific perspective, NRP will increase organ use, reduce organ injury, and improve outcomes. To preserve public trust in organ donation, ethical issues need to be investigated, navigated, and discussed but are not insurmountable. NRP must be conducted within the confines of the UDDA. Finally, communication with donor families is paramount to ensure transparency. Further research is needed to assess families' information needs and communication strategies in a family-centered approach.

FUTURE DIRECTIONS: PROTOCOLIZATION OF TA- AND A-NRP PROCEDURES (JORDAN HOFFMAN AND KRISTOPHER CROOME)

Currently, DCD protocols are developed by individual donor hospitals and procurement techniques are center-specific. The variability in both protocols and techniques can lead to confusion, concerns about ethical acceptability, and lower organ utilization. Standards for both TA- and A-NRP procedures need to be developed and include communication expectations, recording of times and intraoperative events, technical steps, and organ viability assessment. In addition, certification standards for procurement surgeons should be developed like that for other deceased organ donation procedures.

FUTURE DIRECTIONS: RESEARCH (ALEAH BRUBAKER AND ELISA GORDON)

Both qualitative research, which addresses stakeholders' perceptions and experiences with NRP, and quantitative research, which assesses outcomes and other metrics, are essential for the advancement of NRP DCD organ donation. Qualitative research can be used to understand and describe phenomena and human behaviors from an individual's point of view, examining how context (eg, social, cultural, political, economic, historical) shapes processes and events. Through the conduct of interviews, focus groups, direct observations, and case studies, investigators can ascertain the meaning of events or experiences that drive human behaviors to develop and test theories.

There is a paucity of qualitative research that has examined attitudes toward NRP DCD donation in the United States. Two Canadian studies, one on public perceptions and other one on healthcare provider perceptions, assessed cardiac DCD donation with both DPP and NRP through closed-ended surveys with few open-ended

response questions. Public perceptions generally supported the implementation of cardiac DCD protocols, but respondents expressed concerns about the possibility of consciousness during NRP procedures.[30] Healthcare providers expressed concerns that the public would not understand or accept cardiac DCD donation and that restarting cardiac activity after death would be confusing to the lay public.[31] In the United States, research should assess stakeholder perceptions of NRP DCD, focusing specifically on ethnic and racial minorities and religious groups with historically and currently low rates of deceased organ donation. Knowledge gaps with respect to public perceptions include perceptions of DCD donation, perceptions of different procurement techniques, information needs, and the impact of utilization of NRP on public trust in organ donation.

Quantitative research is also necessary for the continued development of NRP in the United States. Current data from the Scientific Registry of Transplant Recipients are limited in collection of recovery and storage modalities, time to initiation of recovery modality, type, and duration of NRP when used and intraoperative laboratory trends for NRP donors. Because national data are lacking, determination of best practices for point of care testing, duration of NRP, thresholds, and definitions of functional warm ischemic time cannot be developed. A dedicated database that collects data on these variables and donor variables (eg, age, body mass index, infectious hepatitis, other risk factors) is necessary for the data-driven expansion of DCD donation that maintains excellent recipient outcomes while simultaneously expanding the deceased donor pool.

CONCLUSIONS

The ASTS is fully cognizant of ethical concerns raised regarding NRP, which mostly focuses on TA-NRP, yet supports the ongoing utilization of both A and TA-NRP. Our society strongly feels that NRP not only saves lives but also offers a donation modality that does not violate essential moral, philosophical, and bioethical medical precepts. Finally, donor and donor family autonomy need to be considered in the ethical assessment of current or future technologies used to expand the donor pool, focusing on defining information needs, ensuring comprehension and voluntariness in decision-making, and minimizing the harms of no donation.

ACHIEVEMENTS, CHALLENGES, AND NEXT STEPS

- This conference *achieved* a consensus opinion on the legal and ethical aspects of NRP by bringing together a multidisciplinary team of experts and laid out an agenda for research and national standard development for NRP in the United States.
- The *challenges* we face include the widespread implementation of technical and nontechnical standards for NRP DCD procurements and a wider national consensus on the ethical and legal acceptability of NRP.
- The *next steps* include the development and implementation of national standards for NRP DCD organ procurement and a centralized database to be able to study the impact of NRP on organ procurement and utilization as well as recipient outcomes.

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