Trauma Surgery & Acute Care Open

Organ donation in the surgical ICU: an American Association for the Surgery of Trauma Critical Care Committee clinical consensus document

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Received 9 February 2023 Accepted 26 April 2023

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To cite: Seshadri A, Cuschieri J, Kaups KL, *et al. Trauma Surg Acute Care Open* 2023;**8**:e001107.

INTRODUCTION

The Critical Care Committee of the American Association for the Surgery of Trauma (AAST) develops clinical consensus documents to provide practical guidance on challenging topics. The basis of these documents is expert consensus after a review of the recent literature to provide up-to-date best practices for the bedside clinician. The Critical Care Committee chose the care of the patient prior to organ donation in the intensive care unit (ICU) as a topic for review.

As is true in any ICU, surgical ICU patients can proceed to organ donation, but this population may be higher in a trauma/surgical ICU due to the presence of patients who have suffered devastating traumatic brain injury (TBI). The care of these patients is complex and requires multidisciplinary team members, including legal or ethical experts in challenging cases. This document addresses several topics relevant to the surgical intensivist to provide the most up-to-date guidance from the available literature in navigating these issues in a thoughtful, empathetic way that honors patient and family wishes as well as provides for life-saving organ donation.

Although varying terminology is used in the literature, we refer to donation as either occurring after neurological determination of death (DNDD) or after circulatory determination of death (DCDD). Death by neurological criteria (DNC) and brain death will be used interchangeably.

METHODS

The AAST Critical Care Committee chose organ donation as a topic for review. A working group was then created from the larger committee, which identified relevant questions for literature review based on the members' review of controversial or developing issues surrounding the logistics of organ donation. This review was done at each author's discretion using society guidelines as well as peerreviewed original research published in the last 10 years. To develop consensus, the content was then reviewed by the working group and then the Critical Care Committee as a whole. Of note, these recommendations are based on best practice expert consensus and are not based on formal processes such as Grading of Recommendations, Assessment,

Development, and Evaluations (GRADE) methodology or Delphi consensus.

LEGAL BACKGROUND

What laws and organizations have codified the rules surrounding organ donation in the USA? Recommendation

The Uniform Anatomical Gift Act (UAGA) established a legislative template for organ donation. Since its passing, the United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN) have created the logistical framework to allow for organ donation across the country.

Discussion

After the establishment of transplantation in the 1960s, the USA established an 'opt-in' system for organ donation. The UAGA, initially passed in 1968 and revised in 1987 and 2006, has provided a template for organ donation legislation adopted by most states in the USA. Key provisions of the UAGA include a provision for first-person authorization (FPA) for organ donation, anatomic gifting, and research, as well as a specific prohibition against legally authorized representatives (LARs) overriding a decedent's documented wish for donation. The UAGA has been modified in some states, leading to variability between organ donation indicators (such as drivers' licenses) and state-specific donor registries. In 1984, the National Organ Transplant Act provided national structure to organ recovery and transplantation, establishing the OPTN as well as regional organ procurement organizations (OPOs), and formally banning the sale of human organs for transplantation. UNOS is a private, non-profit entity which operates the OPTN under contract with the Health Resources & Services Administration.1 Regional OPOs are tasked with identifying donors and securing donation of organs, under requirements for certification, quality, and performance improvement established by the Organ Procurement Organization Certification Act of 2000. Centers for Medicare and Medicaid Services (CMS) regulations largely regulate OPO conduct through defining quality requirements to receive Medicare and Medicaid payments.²

In parallel to the development and regulation of organ transplantation, definitions of death evolved beyond heart-lung criteria (absence of pulse, respiration, and responsiveness) to include neurological criteria, expanding the organ donor pool. The concept of neurological death progressed from its initial formal introduction by the Ad Hoc Committee of the Harvard Medical School in 1968, through the Uniform Brain Death Act of 1978, to the Uniform Determination of Death Act (UDDA) of 1980. The UDDA codified DNC and stated that 'an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead'.3 Recent legal and moral/religious objections to the use of neurological criteria to declare death have been raised. Surveys suggest that up to 60% of intensivists have reported being asked to continue organ support after DNC, with a significant percentage of such requests involving potential legal action.⁵

Various state laws and institutional policies may address elements of the organ donation process differently. Providers should be familiar with their local regulations to ensure compliance and optimal practice. However, in this consensus, we also highlight several practices that call for consistency, including recognition of an individual's desire and eligibility to be an organ donor, application of current best practices to the donation process, and integrating organ donation into conventional end-of-life care with a patient-centered approach.

What is FPA, its legal ramifications, and implications for providers?

Recommendation

FPA laws were enacted with the 2006 UAGA revision and state that if individuals have documented their organ donation wishes, they cannot be revoked except by them. OPOs then work to resolve any disaccord with the LAR to allow for maximal compassion and empathy in the donation process.

Discussion

As the field of transplantation developed, regulation to provide a context for donation in the USA was enacted. The UAGA defines and helps to ensure integrity in the donation process. As of 2017, some version of this legislation has been adopted in all 50 states and the District of Columbia.

Recognizing that individuals may be unable to indicate their wishes at the time that donation is being considered, FPA (also known as 'donor designation') laws were enacted with the 2006 UAGA revision. These laws recognize the essential primacy of individuals' ability to document their wish to become an organ donor and enforce such designations as legally binding. FPA laws exist in every state, which permit organ donation without additional LAR consent if the donors have documented their wishes either via donor registry or card, driver's license, or state identification card.⁶ The UAGA specifically states that 'a person other than the donor is banned from making, amending, or revoking an anatomic gift of a donor's body or part if the donor made an anatomic gift of the donor's body or part'. Furthermore, the UAGA specifies that a good faith attempt should be made to find a patient's LAR, but if they are not 'reasonably available' or there is no LAR present and there is no documented evidence of the patient's choice not to donate, donation can proceed.

However, in the situation where conflict arises between the donor's stated wishes and the LAR's desires, many OPOs will attempt to resolve this rather than implicitly after the donor's wishes. In a 2013 survey of all US OPOs, only 50% had a written

policy for addressing these conflicts; 80% reported honoring FPAs during a dispute. Slightly over half of OPOs reported always after FPA designation, whereas 45% indicated 'in most cases'. The most commonly cited reasons were related to adverse public relations and legal liability.⁸ 9

IDENTIFYING POTENTIAL DONORS

What are the best practices for identification of potential organ donors?

Recommendation

Early identification of patients' wishes and eligibility for organ donation is essential. Referral to the local OPO is a recommended best practice for any patient who is at high risk of imminent death.

Discussion

The organ donation system in the USA is intended to afford every eligible organ donor the opportunity to donate. Early identification of eligibility is essential so that hospitals and OPOs can successfully prepare for donation. In 2021, 68% of organ donors were deceased donors, mostly through donation after DNDD.¹⁰ However, there has been a progressive rise in the number of donations after DCDD with 4190 in 2021, accounting for about 30% of deceased donations. 10 To optimize capture of all potential donors, the CMS instituted federal regulations which require hospitals to notify the local OPO of all imminent and in-hospital deaths.¹¹ It is the responsibility of clinicians to notify the OPO of all potential donors and of the OPO to determine a potential donor's candidacy. Liberal referral to OPOs is encouraged and does not preclude ongoing patient management, including goals of care discussions. A collaborative, patient-centered plan between the OPO and the healthcare team is essential to optimize the probability of donation authorization. The patient's LAR should be approached separately about organ donation around the time of discussion of withdrawal of any life-sustaining treatments, to decouple that decision with decisions about donation, or if the LAR initiates inquiries about donation. A collaborative consensus statement on the management of potential organ donors from the Society of Critical Care Medicine, the American College of Chest Physicians, and the Association of Organ Procurement Organizations recommends that clinicians should notify the OPO within 1 hour if a patient meets specified clinical triggers and that organ donation should be considered as part of end of life decisions.12

Common clinical triggers that prompt referral to an OPO may include:

- ► Identification of a patient that has sustained a potentially non-survivable neurological injury.
- ▶ When a brain death examination is being considered (prior to the examination).
- ► When discussions regarding withdrawal of life-sustaining therapies are being considered (always prior to limiting or withdrawing such therapies).

Accurate determination of DNC (or brain death) is also critical to the donation process. Significant variation in determining DNC exists in the USA despite decades of known best practices. Timely and accurate determination of DNC when present, regardless of organ donation, is essential. Establishing brain death helps providers communicate with families that death has occurred and allows them to begin the grieving process. It has also been noted that confusion and variation around determination of DNC have potential to erode the public trust. The World Brain Death Project, 14 an international consensus,



has thoroughly described the DNC process. We endorse that providers follow established guidelines to improve the standardization and validity of examinations for DNC.

MULTIDISCIPLINARY TEAMS AND FAMILY INTERACTIONS When should OPOs become involved with a potential organ donor?

Recommendation

The OPO should be contacted as soon as donor potential is recognized, based on objective indicators.

Discussion

Early OPO referral is recommended to optimize family care and donor management. Best practice is to refer based on objective clinical indicators, or triggers, which are well described in the literature. 15 16 If death is imminent, the CMS requires that an OPO be informed within 1 hour so they may evaluate a patient for potential organ donation.¹¹ Local OPOs determine the patient's medical suitability for organ donation and obtain authorization for donation from the patient's LAR. Although clinicians and hospital staff may collaborate with the OPO during this process, they must defer conversations with the LAR regarding organ donation to the OPO.¹² In addition to the ethical implications of care providers discussing donation with families, multiple studies have demonstrated increased authorization rates when the donation discussion is held by formally trained OPO staff who approach the LAR with sensitivity and respect and who have detailed knowledge to answer questions about the donation process.17 18

What are best practices in effective communication with families surrounding organ donation and unsuccessful organ recovery?

Recommendation

It is recommended that the timing and method of communication with families about organ donation be optimized, as discussed further. Predonation expectation setting and empathy are critical components of communication when organ recovery is unsuccessful.

Discussion

Ineffective communication is a critical factor associated with failure of authorization for donation; effective communication increases authorization rates. During the past several decades, the rate of referral for organ recovery has ranged from 65% to 99%, but the rate of authorization remains unchanged at under 60%. 17 19 Appropriate and empathetic communication is essential to improving understanding around organ donation. Effective communication begins by acknowledging the family's personal grief and supporting them during their crisis. Organ donation should not be part of initial conversations regarding brain death testing or transitions of care. LARs who are rapidly approached about organ donation can interpret this as inappropriate pressure, and thus may be less likely to consider donation. Once organ donation is discussed, the family should be given time to ask questions and receive additional information.²⁰ It is imperative that displays of empathy and support are provided to allow families to make the best decision about organ donation.²¹ ²² Courses such as Communicating Effectively About Organ Donation (www.ceadtraining.org) and the Organ and Tissue Authority Family Donation Conversation have been designed as scenariobased programs to provide the tools for effective communication.²³ ²⁴ In addition to improving individual conversations,

communication among team members prior to meeting with families is critical to provide the most supportive and empathetic environment possible to both support the grieving process and acknowledge the request for organ donation.²⁵

Appropriate communication is not only essential during initial discussions, but also critical around failed donation attempts. About 25% of potential DCDD donors do not progress to death by circulatory criteria and thus organs are not recovered.²⁴ This can result in the loss of the anticipated improvement to the emotional distress and grieving process for families wishing to proceed with donation.²⁶ ²⁷ ²⁸ Failure in donation results in interruption of the grieving process and thus must be considered in the discussion prior to DCDD. Given the rate of failed DCDD, OPO professionals must be clear in discussion of expectations with families, and both the OPO and healthcare team must be ready to empathetically address potential failure of donation.²⁹

MEDICAL MANAGEMENT OF THE POTENTIAL DONOR What specific interventions are considered best practices in the optimization of the patient as a potential donor prior to brain death?

Recommendation

Patients with devastating brain injury (DBI) should be managed with an initial period of aggressive resuscitation and full support with the goal of physiological stability. Therapies that support hemodynamic stability, end-organ perfusion, and euvolemia will both benefit the patient and preserve the potential of organ donation. Hormone replacement therapy (HRT) in DBI includes thyroid hormone, corticosteroids, insulin, vasopressin, or a combination thereof, with early HRT requiring more study.

Discussion

There are extensive guidelines for the management of identified and confirmed organ donors, but it is less clear-cut which of these management strategies should be applied to patients who have not yet formally transitioned to the donation process. ¹² A reasonable approach may incorporate donor-specific management strategies that also support the clinical goals of resuscitation and stabilization.

A fundamental strategy in caring for patients with DBI who are potential donors is to avoid de-escalating care prematurely. ^{12 30 31} Unless there is clear guidance from the LAR or advanced directives which limit further therapies, or inadequate medical resources, patients with DBI should be aggressively resuscitated to optimize perfusion and normalize as many physiological parameters as possible. This strategy enables improved neuroprognostication, allows time for the LAR to engage in decision making, and may also provide the necessary conditions for formal brain death examination. ³⁰ Together, these strategies help preserve the option of donation. ^{30 32}

The specific element of donor management most frequently employed in patients with DBI prior to brain death is HRT. This includes thyroid hormone, corticosteroids, insulin, and arginine vasopressin, or a combination thereof. The data supporting these therapies are mixed and the physiology is not clearly elucidated, yet studies suggest that the use of HRT in donors may promote hemodynamic stability, improve organ recovery rates and improve graft function and survival. ¹² ³¹ ³³⁻³⁵ A few studies have strongly suggested that early HRT (prior to brain death) improves subsequent organ recovery and function. ³⁶ However, randomized trials are lacking, and there are no prospective studies or formal guidelines showing the proven benefit of early HRT

Insulin for strict glucose control is standard in critical care, and vasopressin is a reasonable choice for a brain-injured patient in need of hemodynamic support, with or without diabetes insipidus. The use of thyroid hormone is recommended in donor management guidelines for donors who have persistent hemodynamic dysfunction or a reduced ejection fraction, and is often used more liberally as some data support a positive effect on donor stability and graft function and survival.¹² Given the pathophysiology of herniation-mediated hemodynamic instability, thyroid hormone treatment in patients who are not yet brain dead has been suggested to promote hemodynamic stability, decrease the negative effects of high-dose vasopressors, and help avoid cardiovascular collapse. The direct effect on disease-specific pathophysiology, the low-risk profile, and the likely clinical benefit makes thyroid hormone therapy reasonable to use in patients with DBI even outside the auspices of donor management. Dosing regimens vary, but a common example for dosage of thyroid hormone is as follows: T4 20 µg intravenous bolus, followed by a 10 µg/hour intravenous infusion or T3 4 µg intravenous bolus, followed by a 3 µg/hour intravenous infusion.12

Corticosteroids, however, have been associated with worse outcomes in patients who had severe TBI; therefore, their routine use in patients who are not brain dead is controversial.³⁷ For those donors who are already brain dead, however, corticosteroids can be used with dosing regimens including intravenous methylprednisolone 1000 mg or intravenous methylprednisolone 15 mg/kg, or methylprednisolone 250 mg intravenous bolus, followed by a 100 mg/hour intravenous infusion.¹²

Other donor-specific management strategies intended to improve donation potential or outcomes, such as invasive monitoring or renal replacement therapy, are best approached in context of the patient's overall goals of care.

Should trauma providers consider a patient's organ donor potential when making decisions about resuscitation in the setting of otherwise non-survivable injuries?

Recommendation

We recommend that a patient's organ donor potential be considered in injury-related end-of-life situations where initiating or continuing resuscitation may stabilize the patient long enough to provide certain benefits to the patient and family, including the possibility of organ donation.

Discussion

About 25% of trauma deaths occur shortly after presentation at the hospital.³⁸ Providers may be faced with decisions about continuing treatment or not, when the patient's survival is unlikely. A common scenario is a patient with DBI after a cranial gunshot wound. One approach is to withhold additional therapies that will not be ultimately life-saving, potentially in an effort to benefit the patient/family by avoiding futile interventions and a prolonged dying process.

Alternatively, continued resuscitation may be beneficial to both patients and their families for several reasons. First, a patient's final outcome may not be determinable based on initial examination. These patients are often in shock and hypothermic, which precludes an accurate neurological examination. The Trauma Quality Improvement Program Best Practices document on TBI recommends continuing aggressive therapy in patients who had severe TBI for 72 hours before limiting therapy or prognosticating.³⁹ Aggressive resuscitation improves patients' eligibility for organ donation and, in some cases, their chance

of survival.^{32 40 41} A multicenter study demonstrated that even in patients with cranial gunshot wounds undergoing cardiopulmonary resuscitation (CPR), 2.1% survived to discharge, and 17.5% of non-survivors were eligible donors.⁴²

Second, stabilization and transfer to ICU give families time to visit, receive information, adjust, and start the grieving process. Similar to family presence during CPR, which is associated with lower rates of post-traumatic stress disorder, anxiety, and depression symptoms, families see for themselves the medical care being provided, which may facilitate acceptance and closure.⁴³

Third, the patient's wishes regarding organ donation may be unknown on presentation. Resuscitation permits time to call the OPO, who will determine donor eligibility and speak with the family to discover the patient's donation preferences. 44 Patients also may have given FPA for donation, which is a valid medical wish and legal document that medical providers are obligated to honor when possible.

How can clinical implications of patient/LAR-initiated treatment limitation be reconciled with optimal donor management principles?

Recommendation

Clinicians should recognize the potential effects of treatment limitations on a patient's ability to donate their organs. The implications of treatment limitations should be discussed by the OPO with the patient's surrogate prior to enacting limitations.

Discussion

Patients' decisions about donation are valid medical choices. The challenge presented by limitation or 'no escalation' of treatments is that it may be detrimental to a patient's wish to be an organ donor. Clarity is best achieved through specific patient/family discussions regarding what life-saving interventions are concordant with goals of care. Decisions about treatment limitations are best made independently of those for organ donation but should not hinder organ donation if that is still desired by the patient/LAR. Although treatment limitations may align with some end-of-life preferences with respect to allowing natural death, patient-centered care should account for all pertinent preferences, not just those regarding survival.⁴⁵

Procedural and institutional safeguards exist to maintain a boundary between survival-directed care and potential donor management, such as the use of an OPO 'designated requestor' distinct from the clinical team to approach LARs regarding organ donation. Additionally, institution-specific and state-specific procedures for declaration of death must be strictly followed to maintain the dead donor rule—the ethical principle that death must not be induced in the service of organ recovery for donation. For example, the National Conference on Donation after Cardiac Death recommends 'not less than two minutes is acceptable and not more than five minutes is recommended' as standard time from asystole to death declaration.

Complex circumstances may arise when non-life-saving therapies (such as steroid or thyroxine supplementation, antibiotic use, or systemic anticoagulation) may not be specifically excluded as care limitations for an individual patient, but which may have salutary effects on organ quality. Many such situations arise related to organ support strategies developed for organ donors who have been declared neurologically dead but who have not yet undergone organ recovery.⁴⁹

From the ethical perspective of respect for patient/LAR autonomy, clearly articulated care limitations should be respected. However, requests for such should be viewed in the



context of the patient's wishes regarding donation. Since treatment limitations may conflict with a patient's desire to be an organ donor through permissive organ damage, it is recommended that an expedited discussion between the LAR and OPO be held to ensure this conflict is resolved. Transparency is important in these situations to avoid discord with the ethical principles of non-maleficence and justice. From the perspective of non-maleficence, procedural and medical therapies viewed as potentially painful and/or suffering-prolonging may harm both patients and their family. From the perspective of justice, the societal interest in maximizing organ donation and transplantation must be tempered with the ethical imperative of maintaining clear and transparent processes around donor identification, authorization, and end-of-life care.⁴

We advocate that organ donation processes be integrated into standard end-of-life care. Since the donation process is aligned with, and dependent on, optimal standard medical treatments, providers can honor the patient's wishes for donation should survival become unlikely. No escalation requests are often made with little notice, making collaboration with the OPO imperative early in a patient's ICU course.

How should providers consider and quantify resource use when treating potential donors with non-survivable injuries? Recommendation

When resources allow, all patients with DBI without a known pre-existing objection to treatment should be aggressively resuscitated for an initial period to maximize the likelihood of potential neurological recovery or the opportunity for organ donation.

The time at which resource use ceases to provide benefit is best determined locally on a case-by-case basis, but a minimum treatment period of 48–72 hours is reasonable in most cases.

Discussion

Guidelines on the resuscitation of non-survivable patients with regard to organ donation endpoints are lacking.⁵⁰ A recent study surveyed trauma surgeons regarding resuscitation practices for organ transplantation. All were willing to intubate; most were willing to start vasopressors (94%) and to transfuse blood (84%) (range 1 to >10 units). Twenty-nine percent would resuscitate for \geq 24 hours, and 6% would perform a resuscitative thoracotomy.⁵⁰

Aggressive management strategies have shown positive effects on organ donation after fatal gunshot wounds to the head and other traumatic mechanisms, including use of blood products, vasopressors, hormone supplementation, and resuscitative thoracotomy.^{32 51} In a single-institution study, aggressive management has lead to a 49% organ donation rate within their identified eligible donors.³²

Resource use should be considered when caring for potential donors with non-survivable injuries. Public opinion is inconsistent on whether it is acceptable to initiate or continue lifesustaining therapies solely for organ recovery, and such dilemmas exist for providers.^{51 52}

A position statement from the Neurocritical Care Society recommends that resuscitation of patients with DBI should not be dependent on the possibility of organ donation³⁰; that is, if resuscitative efforts are futile and no option for organ donation exists, there is no obligation to continue to resuscitate. Patients with DBI should be resuscitated while respecting their autonomy to make decisions about their care. This may mean stopping resuscitation after a point but also may favor ongoing resuscitation if the patient has designated a wish for organ donation. The

position statement also cautions against hasty prognostication, advocating 'repeated examinations over time'.

Benefits of honoring patients' donation wishes, allowing time for family visitation and grieving, assurance of prognosis and non-survivability, and preserving the option of organ donation all favor extending treatment and avoidance of rushed decision making. Catastrophic brain injury guidelines (CBIGs) are standardized order sets and protocols designed to optimize early management in patients with DBI. Their use helps avoid undertreatment bias, and CBIGs have been associated with better achievement of donor management goals⁵³ and number of organs transplanted per donor.⁵⁴

Although there are specific recommendations regarding donor management goals, no established guidelines exist regarding the quantification of resource use when awaiting either brain death or DCDD recovery; rather, these decisions are at the discretion of the provider. Through consensus, we recommend that a minimum treatment period of 48–72 hours is reasonable in most cases, although local hospital needs should be evaluated on a case-by-case basis. Prompt OPO notification should be undertaken in addition to implementation of donor goal-directed therapies. Institutions should prioritize the development of the multidisciplinary resources needed to optimize outcomes in potential DBI organ donors. 12.52.55

CPR PRIOR TO DONATION What is the role of CPR in DNDD and DCDD patients prior to organ recovery?

Recommendation

CPR is recommended for cardiac arrest in brain dead patients awaiting donation to preserve the option of donation. This possibility should be discussed by the OPO with LARs during the authorization process. In DCDD patients, LAR consent should be obtained prior to performing CPR for the purpose of allowing donation to proceed.

Discussion

Patients often declare their stance on the use of CPR for life preservation but rarely do so with regard to organ preservation prior to donation. Decisions regarding the latter are usually made by surrogates on behalf of patients awaiting organ recovery ('donors'), either prior to DNDD or with planned DCDD. The circumstances in which CPR may be used in donors often present ethical and practical challenges to families and healthcare providers. Notably, CPR in donors does not seem to adversely affect recipient outcomes. ^{56–58}

Donation benefits donors by respecting their autonomous medical wishes for donation. In brain dead patients where a plan for donation has been established, intensive management is often needed for organ preservation. ⁵⁹ CPR lies on this management spectrum. However, the visual and physical aspects of CPR may be disturbing or may cause psychological stress in families or providers, even though CPR is much less invasive than the actual organ recovery, which has already been designated. ⁶⁰ The LAR and the medical team should be informed that CPR is included in standard donor management for DNDD, and family support should be provided for this possibility. ⁶¹ Although the issue of CPR in DNDD patients is not routinely discussed in published guidelines, multiple medical societies and several authors have advocated for its use, as detailed in a comprehensive literature review by Dalle Ave and colleagues. ⁶⁰

In DCDD patients where donation authorization has been obtained, patient/surrogate directives regarding CPR should be

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confirmed. DNR directives during initial life-saving care should not be assumed to account for the unique circumstance of DCDD. When donation potential exists, it is imperative that the OPO discuss the option of providing CPR and other treatments for donors and relay this information to the healthcare team. So Surrogates should be offered the option of allowing or declining CPR while waiting for withdrawal of life-sustaining therapy for planned DCDD. In this situation, since CPR is not intended to be life-saving for the donor, it should only be implemented with prior consent. As with much of donor care, compassionate and transparent communication are essential to navigating this ethical challenge.

Contributors All authors were involved in the design, research, and writing of this guideline, as well as in the critical revision of the article. AS and CPM performed the final revisions of the article.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; internally peer reviewed.

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