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Innovations in DCD: Ethical and Legal Considerations for the OPTN, OPOs, Transplant Surgeons, and Recovery Teams

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Abstract

Purpose of Review Donation after circulatory death (DCD) is increasing in the United States, potentially leading to more organs for transplant candidates. In this article, we address how increasing focus on DCD recovery and using novel procurement techniques, combined with new pressures on Organ Procurement Organizations (OPOs) to complete more organ recoveries, creates new ethical dilemmas that must be proactively resolved to preserve community trust in the organ transplant process.

Recent Findings While novel techniques like normothermic regional perfusion and centralizing organ recovery in donor management centers can mitigate some of the technical issues associated with DCD, and recovering organs from unrepresented patients can increase the organ pool, these techniques pose new challenges for defining death and ensuring that organ donation does not unduly influence clinical care.

Summary Pursuing innovative DCD strategies requires adequate collaboration between OPO representatives, ICU clinicians, donor family members, and the public to increase the organ pool while maintaining trust in transplant.

Keywords Donation after circulatory death (DCD) · Normothermic regional perfusion (NRP) · Ethics · Organ procurement organization (OPO) · Donor care unit (DCU)

Introduction

Despite clinical successes in organ transplantation, a lack of sufficient donor organs remains the primary limitation to reducing waitlist mortality. As a result, members of the United States transplant community have advocated for expanding donation after circulatory death (DCD), which remains a low proportion of total organs recovered [1]. DCD recovery is expanding in the United States, increasing in one recent year by 29.9% [2]. Yet there remains significant unexplored opportunity, in large part due to the technical challenges associated with successfully preserving, transporting, and transplanting DCD organs, which experience significant warm ischemic time. While novel techniques like normothermic regional perfusion and centralizing organ recovery in donor management centers can mitigate some of the technical issues associated with DCD, these techniques pose new challenges for defining death and ensuring that organ donation does not unduly influence clinical care. In this article, we will address how an increased focus on DCD recovery and use of novel procurement techniques, combined with new pressures on Organ Procurement Organizations (OPOs) to complete more organ recoveries, create new ethical dilemmas that must be proactively resolved to preserve community trust in the organ transplant process.

Overview of DCD

DCD was the standard organ recovery modality from the inception of transplantation in the 1960s until Brain Death became well established [3]. As acceptance of brain death grew in the U.S. during the 1980s, donation after brain death (DBD) began to replace DCD because of DCD's

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comparatively poor outcomes.[1][5] The almost total shift away from DCD and toward DBD in the subsequent decades did not help address the persistent organ shortage. DCD has long represented huge potential for expanding the organ pool because, while DBD accounts for most organ recovery, [6] most people die by circulatory criteria, not neurologic criteria [7]. But in contrast to DBD, during which the donor's organs remain circulated inside the donor's body, circulation stops prior to DCD, meaning DCD organs deteriorate rapidly. To realize DCD potential, there needs to be a complicated logistical coordination of a decision to withdraw life-sustaining support (wLST), authorization for organ donation, the actual implementation of wLST, then rapid organ recovery, preservation, transport, and transplant. Even if this dance is performed perfectly, traditional (rapid recovery) DCD generally leads to fewer transplantable organs and inferior transplant outcomes than does DBD [8]. The challenges of increasing DCD recovery are complicated by new pressures on OPOs to obtain more organs, which will be discussed more later.

Increasing the supply of transplantable organs through the expanded use of DCD is focused on "controlled" donation after circulatory death (cDCD), meaning patients in hospital-settings who have requested (or whose surrogates have requested) removal of life-sustaining treatment support and are expected to die a very short time afterward.[2][5] Controlled DCD allows for planning and coordination of organ recovery, but the timing of recovery procedures is often still unpredictable. Although the organ recovery process differs across donor hospitals, a DCD donor is usually brought to the operating room after consent for organ donation has been obtained, where ventilation is disconnected and life-sustaining therapies are withdrawn. After the cessation of cardiac and circulatory activity for a standardized wait period, depending on the local protocol, the patient is pronounced dead by a member of the primary team. The organ procurement team then arrives to the operating room and begins organ recovery [3].

But death may not occur right away, causing long periods of uncertainty as to whether the potential donor may actually be able to donate organs. In some cases, the donor may be sent back to the ICU, causing emotional harm to loved ones who have begun the grieving process, and are left without closure. In other cases, if circulation does not stop within a limited period of time, the organs are too damaged for transplant. In this case, the patient dies without fulfilling their expressed or implied desire to donate organs to help someone on the transplant waitlist [9]. Unsuccessful DCD results in more than disappointment of potential recipients and loss of hospital resources; it represents an inability to honor the donor's memory and character, and threatens the family's ability to make sense of tragedy and the loss of their loved one [10]. Clinically, it is challenging to identify suitable DCD donors and understand how to effectively manage the consequences of warm ischemia caused by a prolonged lack of blood flow, and do so in a way that is ethically and legally acceptable [11]. As pressures to increase the volume of transplantable organs rise, OPOs may look to the promotion of successful DCD recoveries as a method for improving their performance, but improving DCD outcomes will require the effective use of novel and ethically challenging technologies and processes.

OPO Oversight

OPO Accountability

Reflecting the need to increase the organ supply, there are new regulatory pressures on OPOs to expand organ recovery in their donor service areas. Increasing DCD is among several strategies OPOs are employing to meet their new mandates [2]. This pressure, combined with the unique logistical requirements of DCD, is creating new stress points in relationships between OPOs and donor hospitals, and potential challenges for preserving public trust in transplantation. Regulatory changes designed to increase the organ pool might be incentivizing organ recovery decisions that strain stakeholder relationships.

Transplant centers and OPOs are regulated by the Centers for Medicare and Medicaid Services (CMS) conditions of participation and conditions of coverage requirements. Within these, OPOs must meet performance standards or risk losing their CMS certification and donation service area. CMS is charged, under federal law, with conducting surveys of OPOs and re-certifying them every four years based on whether or not they meet outcome and process measures, which determines whether they may receive payment for services from Medicare and Medicaid. If they are decertified, their donation service area is opened for OPO competition or assigned a qualified OPO to serve the area.

[1] Whereas brain death is defined as "irreversible cessation of all functions of the entire brain, including the brain stem," circulatory death requires "irreversible cessation of circulatory and respiratory functions." [4] Patients who suffer severe brain injury but do not fulfill the criteria for brain death may still be organ donors if the patient, by advance directive, or the patient's family, decides to withdraw life support, resulting in the cessation of circulation.

[2] Controlled donation can be contrasted with "uncontrolled" donation, during which patients who have suffered unexpected cardiac arrest are proximate enough to a hospital for catheters to be rapidly inserted to cool the organs in time for recovery.

New CMS Conditions for Certification

In November 2020, the CMS issued a "final rule", updating the OPO conditions for certification. The final rule would revise the outcome measures for assessing OPO performance to ensure that they are "transparent, reliable, and enforceable; support higher donation rates; help shorten transplant waiting lists; reduce discarded but viable organs; and increase safe, timely transplants." [12].

Key changes to the conditions for certification include: A modified definition of a "donor" to mean an individual from whom an organ is transplanted, not just procured for transplant; a requirement to pursue all potential donors, even those who are only able to donate one organ; and importantly, OPOs risk decertification if their performance is significantly below the median in their donation or transplantation rate. At the end of each recertification cycle, OPOs will now be evaluated based on performance for both the donation rate and transplantation, and placed into performance tiers. Tier I will include the top 25%, which will automatically be recertified for another four years, with the next highest performing OPOs placed in tier II and required to compete with higher performing OPOs to retain their service areas. The lowest performing OPOs are placed in tier III, and replaced by a better performing OPO. The performance metrics do not take into account unique organ recovery challenges that some OPOs face in specific donor service areas. When OPOs in tier III are de-certified, it is unclear what will incentivize a high performing OPO to assume responsibility for these challenging donor service areas. Rather than OPOs self-reporting their performance, CMS will now publish their data on OPO performance in an effort to increase transparency.

Implications: New Responsibilities

The addition of these performance tiers creates a system of competition among OPOs with little opportunity or support for low-performing OPOs to improve. Broadly, these changes create new responsibilities for OPOs, which are traditionally responsible for identifying potential donors, obtaining consent, implementing organ allocation/distribution processes and ensuring that organs are recovered safely and efficiently to allow timely transplantation [13]. OPOs have not historically been subject to the same regulatory scrutiny as transplant centers, but now face real risk of decertification and dissolution if they do not meet expected performance metrics. There is unprecedented pressure on OPOs to identify all potential organ donation opportunities with significant increased attention to DCD. Some of these donation opportunities are ones that OPOs should have always pursued, and others might press too hard on the boundary between patient care at the end of life and organ donation, thus straining relationships with hospital partners and jeopardizing public trust.

OPOS Pursuing Ethically Nuanced Organ Recovery Advancements

This increased competition among OPOs to achieve the CMS-determined top performance standard is intersecting with a move to increase utilization of DCD organs in the transplant community. While intended to improve accountability, performance metrics may be leading to more aggressive behavior in securing organs for waitlisted individuals. As a result, these new standards for certification may be incentivizing recovery strategies, which require in-depth evaluation and collaboration with community and clinician voices. These strategies potentially include pursuing innovative but ethically nuanced procurement procedures like normothermic regional perfusion (NRP), seeking authorization for DCD from unrepresented decedents, and performing DCD in donor management centers.

Expanding DCD through NRP

Advantages of NRP

Organs recovered from a donor after circulatory death have undergone oxygen deprivation after the heart has stopped beating, causing decreased organ quality and a lower quantity of organs to be transplantable from a singular donor. Static Cold Storage has been the standard DCD organ preservation methodology for many decades, but recent use of perfusion systems has shown promise in improving outcomes for DCD organs. [8]. As a result, normothermic machine perfusion (NMP), and normothermic regional perfusion (NRP) have been piloted as strategies for improving both utilization of DCD organs and transplant outcomes, reducing the amount of DCD organs that are discarded and increasing graft survival [15]. Both NMP and NRP are contributing significantly to an increase in high quality organ recovery, however, NRP poses unique ethical concerns.

NRP is a technique for re-circulating organs inside the donor's body using a modified extracorporeal membrane oxygenation circuit or modified cardiopulmonary bypass circuit after circulatory determination of death and the occlusion of blood flow to the brain. NRP demonstrates several clinical advantages over traditional DCD recovery: (1) continuous warm blood perfusion inside the donor's body, reducing damage from warm ischemic time, and restoring organ function and homeostasis; (2) more organs can often be recovered from a single donor; and (3) enabling the visual

assessment of the viability of the heart and other organs in a non-ischemic state (compared to direct static cold storage) before retrieval [16, 17]. It has also been described as a more cost-effective procedure in comparison to ex-situ perfusion techniques like NMP [18].

While there is pressure to increase the utilization of DCD, thereby motivating increased use of innovative procurement procedures like NRP, this utility interest must be considered with respect for the values of potential donors, represented by their advance directives and surrogate decision makers, and balanced with the need to preserve and promote community trust in transplantation. As OPOs increase facilitation of NRP, they must proactively ensure that it aligns with donor and public beliefs.

Ethical Considerations Surrounding NRP

Despite demonstrated clinical advantages, there remain significant ethical concerns about NRP. These stem from the potential for violations of the principle of nonmaleficence (do no harm), respect for persons (which includes respect for autonomy), and utility. "The principle of nonmaleficence is important for maintaining public trust and requires compliance with the Dead Donor Rule, which requires that patients must be dead at the time of organ procurement (i.e. meet criteria for brain or circulatory death) and that organ donation does not cause death." [19].

Prior to initiating NRP, the donor is declared dead by circulatory criteria, meaning that circulation has irreversibly ceased. When NRP begins, circulation is reinitiated (including heartbeat during thoracoabdominal NRP), which some believe undermines the prior determination of death. If we accept this, the recovery of organs becomes the actual cause of irreversible circulatory cessation and is thus the actual cause of death, which violates the Dead Donor Rule [20].

NRP also challenges the scope of professional norms by expanding surgeon, nurse, and perfusionist involvement in how they engage with a dead person's body. For example, when organ procurement surgeons block blood flow to the brain, they intentionally occlude cerebral perfusion. In doing so, some argue they are either actively keeping a dead person (declared so by cDCD) neurologically dead, or worse, causing the death of the donor by neurologic criteria. This role introduces questions about the moral agency of procurement surgeons, especially in the case that they are uncomfortable performing NRP and occluding cerebral vessels, but are required to do so if NRP is more effective than other forms of DCD procurement.

Finally, there are concerns about whether the occlusion of blood flow to the brain during NRP is sufficient to ensure that the donor does not in fact experience any harm. Despite ligating the aortic arch vessels, there might remain collateral blood flow to the brain via other channels including through the spinal column. Despite prior anoxic injury to the brain, some are concerned that reinitiating circulation could thus restore sufficient brain recirculation to restore brain activity and thus experience. This has led to refinement of NRP protocol including venting the vessels after ligation to open the circulatory system to atmospheric pressure, which should cause any collateral flow to drain before reaching the brain [21].

There remains significant debate about these ethical considerations of NRP in academic literature. Some argue NRP is merely reperfusion for purposes of organ preservation and is consistent with the legal determination of death, and that occluding blood flow is not ethically distinct from withdrawing life-sustaining treatment [22]. Regardless, there are many people across hospital leadership, ICU care, risk and compliance, and ethics committees who remain concerned. And despite calls for transparency and public engagement, [23, 24] there has yet to be published exploration of public or donor family perceptions of NRP.

In a 2022 survey on OPO practice of DCD recoveries, 83% of surveyed OPOs had overseen NRP heart procurements [25]. As an increasing number of OPOs seek to facilitate NRP, decisions must be made about how to ethically implement this technique, including how to seek authorization from family members, and how to perform the recovery safely. Several OPOs pursuing NRP are receiving push-back from hospital partners that share the ethical concerns described above. Without a collaborative approach to NRP decision-making, OPOs risk compromising trust among key stakeholders. This could have consequences beyond recovery of organs in one NRP case – it could stoke distrust among hospital staff leading to delays in donor referral, limiting access to operating room time, and other key elements of successful organ recovery.

Donation from Unrepresented Deceased

Uniform Anatomical Gift Act (UAGA) Provisions

In addition to improving outcomes from recovered organs, OPOs are also under pressure to identify more potential donors. One source of potentially less-explored donors are those without anyone to represent their wishes and values. If a patient is unidentified or next of kin is "reasonably unavailable", as determined by a well-documented "reasonable" search,[3] and there is no documented evidence of the decedent's choice not to donate, the Uniform Anatomical

[3] This may include checking personal belongings, local police missing persons reports, fingerprinting of decedent, questioning of persons visiting the decedent before or after death, and social media, etc., but, if patient's identity is unknown and the patient dies, the responsibility

Gift Act (UAGA) stipulates that anyone with the authority to dispose of the decedent's body may authorize an anatomical gift [26]. Hospital administrators are included in this hierarchy of who can authorize an anatomical gift. They are legally protected, and immune from liability for actions taken in accordance with the provisions under this act or the applicable anatomical gift law of another state [26].

Pursuing Unrepresented Donors and Impact on Community Trust

With new efforts to encourage competition among OPOs for increased rates of transplantation, there may be unintended pressure on OPOs to perform less than fully diligent searches for families before approaching hospital administration for donation authorization. Should the search be less than comprehensive and a family member arrive to learn that their loved one's organs were donated without next-of-kin authorization, [27] harm could come to families of the deceased, which could promote distrust in the organ transplant system. While these changes were intended to increase the supply of transplantable organs, long-term impacts to community trust may result in the opposite.

There are additional concerns for unrepresented patients who do not progress to death by neurological criteria. Under these circumstances, most Health Care Decisions Acts allow the attending physician, with confirmation from a consulting physician, to make a decision to withdraw life-sustaining treatment [28]. Prior to withdrawal, these patients (as with all patients) are supposed to be referred to the region's OPO for organ donor evaluation. Should hospital administration be allowed to authorize DCD organ recovery from unrepresented patients, when the hospital is also making a decision to withdraw life-sustaining treatment from these patients? The lack of personal representation of these patient's values magnifies the possible conflict of interest that arises when the hospital staff are tasked with making the withdrawal decision based on the patient's best interests, while a hospital administrator (often the CMO) is simultaneously tasked with deciding whether to authorize organ donation [29]. While it is possible that many such patients would have wanted to donate had they the capacity to express such a wish, without representation it is almost impossible to avoid the appearance that these patients' end of life care could be unduly influenced by organ recovery intentions.

Donor Care Units

Another innovation that poses ethical challenges for OPO expansion of DCD recovery is the development of Donor Management Centers, or Donor Care Units (DCU). DCUs are "dedicated clinical facilities focused on providing optimal and efficient care of organ donors prior to organ donation as well as the most advanced organ recovery techniques, which can improve the opportunities for organs to be successfully transplanted into waiting recipients." [30].

Individuals who have authorized organ donation and meet donation criteria could be transferred from a hospital intensive care unit (ICU) to a dedicated DCU, where donor care, organ health management, matching/allocation and recovery will occur [30]. These free-standing centers exist to facilitate efficiency in and availability of transplantation, a move supported by a recent National Academies recommendation that each OPO establish their own organ recovery center [31].

While DCUs can "increase cost-effectiveness in organ procurement," and avoid "the complications and delays of organ procurement in a traditional hospital setting," they also increase logistical complexity and the challenge of ensuring that organ donation intentions do not unduly influence the delivery of end of life care [1].

Ethical Challenges of OPO-based DCUs

Hospital-independent, OPO-based, donor management centers cannot withdraw life sustaining therapy and declare death, but they can care for the bodies of those who were previously declared dead in-hospital. Controlled DCD presents the complication of a legal and ethical inability to transfer a living patient to a site where the clinician withdrawing life sustaining therapy could also be affiliated with the OPO. In the case of NRP, however, ECMO technology permits perfusion of organs for an extended amount of time, allowing a declaration of death to occur in-hospital, and potentially the transfer of the deceased mechanically perfused donor body to an out-of-hospital donor management center. At the DCU, the condition of the deceased donor may be sustained without the limitations of a standard operating room, and outside of hospital guidelines. The existing ethical concerns surrounding NRP can thus be further complicated by transferring the NRP donor to a new location, creating potentially misleading optics.

Transferring a dying or deceased patient for the sole purpose of efficient organ donation creates its own unique ethical challenges, and how DCUs might adapt to the normalization of NRP is not clear. Questions surrounding the appropriate safeguards to guide the care of bodies, consent for transfer, and respectful donor management are critical, as transferring a potential organ donor to a separate facility can have implications for the donor's family and loved ones, and the clinicians tasked with caring for these bodies. Will organ donors, their surrogates, and care team have

of the disposition of the body falls upon the coroner, medical examiner and/or hospital administrator.

agency in determining where the organ procurement will take place, particularly if there are differences in outcomes between DCUs [32]? Will they be fully informed about what recovery methods are proposed, and/or be allowed to decide against techniques with which they have concerns? While these questions remain unanswered, new standards for OPO certification could compel the increased use of these utility-maximizing centers, especially while an over five-fold variation in organ recovery from DCD donors exists across the nation's OPOs. This variation has fostered recommendations that low-performing OPOs look to DCUs to allow transplants to occur without the challenges and time constraints of an ICU, especially in hospitals with less familiarity with organ donation [1].

Ethical Challenges of Hospital-based DCUs

There are also examples of DCUs that are hospital-based, which makes it possible for a patient who has not yet died to be transferred to the DCU where life-sustaining treatment will be withdrawn. This can cause additional concern or confusion among hospital staff and family members. If organ recovery is contingent on transferring the patient to another facility, family members and the patient's care team might feel conflicted about the decision to donate organs. If the family has developed rapport with the care team and become comfortable in this environment, they might not feel confident that the new facility will deliver compassionate care during extubation, especially when organ donation is intended. A host of questions might need to be answered, including: Whether the family will get to travel with their loved one to the new facility; will they be allowed in the room during withdrawal; what if the family does not feel comfortable about withdrawal in the OR; will NRP be performed at the DCU. If the family expresses concerns about any of these issues regarding transfer of their loved one to a hospital-based DCU for withdrawal of life-sustaining support and DCD recovery, the OPO will need to respond compassionately and appropriately.

Consider the following case. A patient is a registered organ donor, on a ventilator, and will not progress to death by neurological criteria. The family has made a decision to withdraw life-sustaining treatment. This patient is at a particular hospital where the OPO protocol is to transfer all donors in the region to the neighboring hospital-based DCU. When the family learns about the impending transfer, they get concerned. They do not want to uproot their loved one and delay the planned withdrawal. The OPO asserts that, legally, the patient's donor designation must be honored and in order to honor this decision, transfer must take place. How should the patient's care team respond? What are the actual rights of the family in terms of reconciling the decision to withdraw life-sustaining treatment with their loved one's donor designation? What if the family asserts that their loved one would not have registered to donate had he known this would be the means by which his organs would be donated? How the OPO representatives respond in this kind of situation, and how various stakeholders are brought to the table (ethics committee, general counsel, risk and compliance, CMO, OPO), will have significant implications for how hospital staff and donor families perceive and trust OPOs and organ donation.

Conclusion

Preserving Trust in the Organ Donation System

All deceased organ donation and transplantation rests on a fragile foundation of public trust, and it is essential that new pressures to recover more organs do not unintentionally dislodge this foundation. While efforts have been made to increase public awareness of deceased organ and tissue donation, some individuals' distrust in the healthcare system in general, or distrust in organ donation in particular, has led to lower donation rates. The perception that clinicians may move too hastily in declaring death, authorizing donation, withdrawing life sustaining treatment, or in any action which prioritizes the potential for transplant over end of life treatment for a patient, is a barrier to trust in the transplant process [33]. Increased competition for OPOs to out-perform each other may result in the premature adoption of strategies for increased utility without sufficient communication and collaboration with donor families and hospital staff. These strategies, including the use of procurement methods like NRP, pursuing donation from unrepresented decedents, and the adoptions of DCUs, should only be advanced with public trust and support. Addressing these challenges is critical to continue broadening DCD utilization, which has already significantly expanded the organ pool leading to more life-saving transplants.

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