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Ethically Informed Pragmatic Conditions for Organ Donation after Cardiocirculatory Death: Could They Assist in Policy Development?

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ABSTRACT

The modern practice of organ donation after cardiocirculatory death (DCD) emerged in the 1990s as a response to the alarmingly wide gap between the number of transplantable organs available through organ donation after neurological death and the urgent organ transplantation needs of persons in end-organ failure. Various important ethical dimensions of DCD have been considered and debated by prominent organ donation/transplantation theorists and clinicians.

In this article, consideration of some of these ethical elements provides a foundation for a proposed set of ethically informed, pragmatic conditions that could assist in the development of health policies to guide the practice of organ donation after cardiocirculatory death.

INTRODUCTION

Although organ donation after cardiocirculatory death (DCD) is now practiced extensively in North America and elsewhere, organ donation/transplantation (OD/T) theorists and clinicians remain engaged in a variety of debates about issues of relevance to this practice. These issues include disagreement about the interpretation of the cardiocir-

culatory definition of death and uncertainty about the determination of death for the purposes of DCD. Partly as a result of these differences, DCD practices vary somewhat, and the procedural policies that guide practice often pay suboptimal attention to the ethical dimensions of organ donation in this context. In this article, unresolved ethical issues and ethics-related questions of particular relevance to DCD are briefly examined. One under-explored issue concerns the "live-dead" moral distinction between the status of DCD and brain-dead donors and how this distinction impacts consent-to-donate obligations. On the basis of a consideration of these issues and questions, a set of pragmatically achievable conditions is proposed that could be potentially incorporated into healthcare policies that direct DCD practice. A key condition sets out what, in the author's view, constitutes a comprehensive informed consent process for DCD. Given that OD/T theorists, including Franklin Miller, Robert Truog, and Dan Brock, have put strong emphasis on "valid consent" as a condition for the ethical acceptability of OD/T, it is crucial to get this consent process "right."¹

For the purposes of this article, the practice under consideration is controlled DCD, in which a very ill, but not brain dead, individual has been cared for in a critical care setting and, after withdrawal of life-sustaining treatment, there is an interval of time between cessation of cardiocirculatory function and declaration of the donor's death. Such an interval is

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not required in organ donation after neurological death, because the donor is considered to be irreversibly *factually* dead after brain death has been formally determined.

EVOLVING ORGAN DONATION PRACTICES

In the early days of organ donation and transplantation—from the 1950s to the mid-1960s—the death of a potential organ donor was determined on the basis of then-accepted cardiopulmonary criteria. Various concepts of brain death were introduced in the early to mid-1960s, and, by 1968, the neurological determination of death emerged as the standard for the purposes of OD/T, on the basis of an influential report authored by an *ad hoc* committee at Harvard Medical School that defined death as whole (integrative) brain death—that is, the irreversible loss of all functions of the brain, including cortical and brain stem functions.² This change in practice coincided with the emergence of the *dead-donor rule*, that states that vital organs (those necessary for sustaining life) can only be procured from dead bodies,³ what George Khushf refers to as the first pillar of current OD/T policy.⁴ The neurological determination of death continues to be perceived by relevant professional communities and the public at large as an appropriate method for determining the death of a potential donor.

Following and consistent with recommendations of the U.S. President's Council on Bioethics, the second pillar of OD/T policy—namely, the dual definition of death (death is constituted by the irreversible cessation of cardiocirculatory function or the irreversible loss of whole brain function)—emerged and was widely adopted for the purposes of OD/T.⁵ The modern practice of DCD began in the 1990s, as a response to the wide disparity between the number of organs that were accessible through donation after neurological death and the number of individuals with end-organ failure who were in urgent need of a transplantable organ. According to Alister Browne, the motivation to pursue and standardize DCD was “to expand the donor pool by including in it patients who are in hopeless conditions but who are not dying because of brain injury and hence will not suffer the neurological death necessary to become heart-beating donors.”⁶

SELECTED ETHICAL CONSIDERATIONS

In this section, a number of ethically related concepts and considerations of relevance to DCD are

briefly explored. These concepts and considerations inform the establishment of a proposed set of conditions that could potentially assist in the development of health policies to guide DCD practice.

Social Utility

It is widely recognized by theorists that the primary ethical justification for OD/T practices is utilitarianism (a version of consequentialism), that holds that persons are obliged to decide and act so as to produce the greatest good for the greatest number. In this context, the desired important *good* is health benefit, in the form of enhanced duration and quality of life, for organ recipients. As Andrew Sneddon indicates, “the most fundamental reason to acquire organs at all is utility,”⁷ while Robert Arnold and Stuart Younger speak of this motivation as the “irresistible utilitarian appeal of organ transplantation.”⁸ Proponents of OD/T also sometimes reference values of efficiency and “healthcare sustainability” in making the claim that OD/T results in a better health benefit “bang” for the limited health resource “buck,” when compared to the therapeutic benefits and financial costs associated with alternative life-sustaining technologies such as prolonged renal dialysis.

Khushf comments that, in the context of OD/T, considerations of utility that exist around “optimizing the number of available organs” have tended to “push” death criteria to the “near side” of the dying process. And, in his view, countervailing considerations of respect (for persons) and “strong individuality concepts” have had a tendency to push criteria to the “far side” of the dying process.⁹ A similar tension plays out in the current uncertainty and disagreement about how much non-interventional time is required between cessation of cardiocirculatory function after withdrawal of life-sustaining treatment (WLST) and declaration of death in the DCD context. These tensions and related competing obligations are addressed in later sections of the article.

Conflict of Interest

An ethically related consideration of theoretical and practical interest in the OD/T context is conflict of interest. A conflict of interest exists in circumstances when a person's or an organization's primary obligation is, or could be, influenced by a secondary interest. With reference to OD/T, Robert Steinbrook comments, “to avoid obvious conflicts of interest, neither the surgeon who recovers the organs nor any other personnel involved in the transplantation of the organs can participate in end-of-life care or the declaration of death.”¹⁰ Most clini-

cians recognize and acknowledge that the early participation of health practitioners on the transplantation side, whose primary goal is to meet the urgent, therapeutic needs of potential organ recipients, constitutes a legitimate conflict of interest. For this reason, it is a widely accepted, modern practice in North America to separate (clinical and patient/family) decision making about WLST from subsequent approaches to substitute decision makers about potential organ donation. Unlike some of the other ethical elements of OD/T, this conflict of interest consideration (and its effective management) is one aspect of OD/T practice that is importantly guided by a relatively straightforward and accessible ethical and health law concept.

Concerns about Transparency and Openness

There is limited comment and critique in the literature regarding the less-than-optimal transparency about what OD/T actually entails.¹¹ Quite understandably, educational and promotional efforts aimed at members of the public typically focus on the concrete benefits of OD/T to individuals with urgent health needs (and, to a lesser extent, donor families), and tend to be rather “light” on the specific details of OD/T practices. This may be due to a belief that fewer individuals will express an interest in donating their organs if they are fully informed about OD/T procedures. A review of the literature failed to reveal existing empirical support for a claim that enhanced transparency about OD/T procedures leads to a reduction in the rate of organ donation. Current practice around disclosure to members of the public about OD/T could also be influenced by a belief among healthcare providers (HCPs) that disclosure does not need to be highly detailed when decisions are being made about the disposition of dead bodies.

Another factor that could contribute to a lack of transparency is the concern that it may not be in the best interest of members of the public and HCPs to become aware of the complex philosophical debates and disagreements about death criteria and the status of potential donors at the time of organ procurement. James DuBois has commented that significant harms can result from fostering doubts about these matters, which may include the generation of unnecessary distress and a possible reduction in the rates of organ donation.¹² Although these projected burdens seem possible, they do not provide clear rationales or justifications for less-than-full transparency about the nature of OD/T procedures, including the use of pre-mortem investigations and interventions in DCD practice.

Disagreement about Interpretation of the Cardiocirculatory Definition of Death

Disagreement about interpretation of the cardiocirculatory component of the previously described dual definition of death has been recently addressed in the literature by prominent OD/T theorists and clinicians.

One primary focus of debate relates to the importance and meaning of the descriptor *irreversible* in the definition of death. In scientific and ordinary usage, to have the property of *irreversibility* means that the condition under consideration can never be reversed.¹³ Applying this interpretation to the DCD context, *irreversible* cessation of cardiocirculatory function exists when a person’s cardiocirculatory function cannot be reversed under any circumstances. However, such an interpretation is inconsistent with the way death is determined in current DCD practice because, after the passage of a usually rather short period of time (for example, two to five minutes) between cessation of cardiocirculatory function after WLST and the declaration of death, autoresuscitation (spontaneous return of cardiocirculatory function after assumed clinical death) is at least theoretically possible. It is also conceivable that cardiopulmonary resuscitation efforts, if attempted, could restart the heart and circulation.

Current scientific research to support the frequency of autoresuscitation after assumed death is weak.¹⁴ James Kirkpatrick and colleagues comment that “existing empirical data cannot confirm or disprove a specific interval at which the cessation of cardiopulmonary function becomes irreversible.”¹⁵ With specific reference to DCD practice, the longest reported interval between cardiac arrest and autoresuscitation has been about one minute (as of 2010).¹⁶

Some proponents of DCD contend that an acceptable interpretation of the definition of death for DCD purposes is that the cessation of cardiocirculatory function following WLST is permanent in a normative sense, that is, cardiocirculatory function cannot be restored due to the obligation of HCPs to respect existing ethical and health law norms. This is because, in most countries, cardiocirculatory function cannot be restored after a decision has been made through a process of informed consent to permanently withdraw life support. James Bernat considers this sense of normative permanence to be a valid surrogate for *irreversibility* in the DCD context.¹⁷ Don Marquis argues against this claim in support of his contention that “DCD donors are not known to be dead,” that is, without neurological determination of death, sufficient conditions (includ-

ing physiologically permanent *irreversibility* of cessation of cardiocirculatory function) for declaration of death are not met.¹⁸

For the purposes of this article and its focus on ethically informed pragmatic conditions for DCD, a normative interpretation of the cardiocirculatory definition of death seems adequate, given that the context under consideration is a practical, clinical one in which norms regarding health law and ethics guide the decision making of affected parties. However, the question of whether the donor is *dead* on the basis of permanent irreversibility of cardiocirculatory function at the time of organ procurement remains important and relevant in discourses about health policy, which rightly questions whether existing DCD policy should be modified—up to and including the potential discontinuation of this OD/T practice. That being said, in a modern world of rapidly emerging, highly technical health interventions in which the balancing of competing ethics obligations is often only attempted retrospectively, arguments in favor of discontinuing existing DCD practice on the basis of irreversibility and/or other theoretical considerations will have to be both strong and understandable to the general public if they are to be effective in countering the perceived obligations of HCPs and society as a whole to meet more of the urgent needs of persons in end-organ failure than can be met with the exclusive use of a neurological definition of death.

Uncertainty about the Determination of Death

In the past decade, some theorists have challenged the scientific validity of the neurological determination of death and the utility of the dead-donor rule. It is now known that some persons who meet the criteria for neurological determination of death continue to perform a variety of complex, integrative biological functions including metabolism, hormonal balance, infection control, and fetal gestation. Because of this, Miller, Truog, and Brock consider brain death to be a “moral fiction,” that is, a false belief motivated by considerations of utility regarding OD/T.¹⁹

With reference to the determination of death for pragmatic DCD purposes, there is uncertainty in the literature about what is an acceptable time interval between cessation of cardiocirculatory function following WLST and the declaration of death. Internationally, there exists considerable variability among DCD practices in the specified amount of minimally required time (from 75 seconds to 20 minutes²⁰). The motivation for keeping this time interval short is a practical one: the longer that potentially transplant-

able organs have less than optimal blood supply between WLST and transplantation, including the interval when there is no blood supply between cessation of cardiocirculatory function and the declaration of death, the greater the chance that functional viability of the organs will be compromised.²¹ However, despite the validity of this rationale for keeping the time interval short, enough time needs to elapse between cessation of cardiocirculatory function and the declaration of death for the potential donor to be considered *factually* dead by HCPs and the public (see the subsequent section).

“Live-Dead” Distinction between the Statuses of DCD and Brain-Dead Donors

An under-explored philosophical issue of particular relevance to consent-to-donate obligations is the lack of awareness and clarity about the implications of the “live-dead” moral distinction between the statuses of potential DCD and brain-dead donors. From an ethical perspective, there is a significant difference in the statuses of these two types of donors after a decision has been made to withdraw life-sustaining treatment. In DCD circumstances, the person from whom organs are to be procured is not brain dead, that is, the person does not meet the criteria for neurological determination of death in the time interval between the making of a decision to WLST and the declaration of death. Therefore, during this time frame, pre-mortem OD/T-optimizing investigations and interventions to determine and preserve organ viability are happening to a live person. There is a widely accepted, Kantian-derived proscription against treating a person “as merely a means to an end.” This applies, in the context of DCD, to the use of pre-mortem investigations and interventions that are intended to determine/preserve organ viability but do not provide any therapeutic benefits to the still-living, potential donor. In these circumstances (as opposed to donation after neurological death), it could be argued, on a theoretical level, that the potential donor is being used as merely a means to the recipient-benefit ends of organ transplantation.

The reader may be wondering how various Kantian considerations that inform and constrain how persons are to be treated are of relevance to the formulation of ethically informed pragmatic conditions for the practice of DCD. Existing societal norms based in ethics and health law require that Kantian obligations of *respect for persons*—which are primarily instantiated in healthcare through the provision of support for the individual autonomy of patients—must be met by HCPs. That is, capable pa-

tients and substitute decision makers must be fully informed regarding, and make conscious choices about, the potential use of medical treatments and interventions. Such widely accepted consent obligations are considered weaker by some when the proposed actions and procedures are to be performed on dead bodies.²² Consistent with this difference, in my view, a higher moral and legal standard of informed choice is needed for DCD (in which a living person is undergoing investigations and interventions between the decision to WLST and the declaration of death) than for organ donation after neurological death, in which such investigations and interventions are happening to an irreversibly, *factually* dead body. This distinction informs some of the content of a proposed optimally informed consent process for DCD described in Condition D of the subsequent section.

DCD proponents could make the claim that any potential harms accruing to a living potential donor from nonbeneficial investigations and interventions are at least partially offset by the furthering of the potential donor's autonomous decision to donate his or her organs. However, such a choice by a capable person must be reasonably informed. The affirmative signing of a donor declaration indicates a general preference by the signer to donate his or her own organs after he or she has died. For reasons described earlier, there is typically no reference in such donor declarations or in the content of OD/T public education/promotion initiatives to the non-therapeutic investigations and interventions that happen to the living donor prior to the declaration of death in DCD circumstances. Given this, a potential donor's wishes about the use of pre-mortem investigations and interventions in this context are typically unknown to the substitute decision maker. Health law scholars Jocelyn Downie, Chantelle Rajotte, and Alison Shea comment that "consent to pre-mortem transplantation optimizing interventions cannot be considered implied by [general] consent to organ donation."²³ Joseph Verheijde and colleagues argue that "allowing temporary organ-preservation interventions without expressed consent is inherently a violation of the principle of respect for a person's autonomy."²⁴

PROPOSED ETHICALLY INFORMED PRAGMATIC CONDITIONS

Prior to the availability of sophisticated life-sustaining technologies in the mid to late 1900s, the determination of a patient's death by his or her attending physician through (then) standard medical

practice was not usually questioned by HCPs or members of the public. As a result of medical and legislative support for the neurological determination of death and the partial success of promoting OD/T practices, the public has come to accept that brain death *is* death, despite the discordant presence of a warm body and beating heart from the declaration of neurological death until organ procurement. To date, despite the forceful, radical critiques of Dick Teresi,²⁵ theoretical debates about whether a potential donor, who is declared brain dead, is irreversibly factually dead have not significantly affected the attitudes of the general public about OD/T, nor become a conscious, overriding concern for HCPs who are actively engaged in OD/T practices. As such, there continues to be broad public and health professional support for the neurological determination of death.²⁶

As a result of the recognized potential for DCD practice to narrow the critical gap between the supply of and demand for scarce transplantable organs, it seems unlikely that this well-established OD/T practice will be abandoned in the future, despite ongoing theoretical debate and disagreement about such issues as "the reversibility objection."²⁷ Given this, perhaps attention should be paid to the answering of a practical, ethically related question, that is, given current theoretical and clinical understandings of the practice, what pragmatic conditions would make it ethically acceptable to procure organs through DCD? In my view, an adequate response to this question is constituted by:

1. A normative interpretation and understanding of the definition of cardiocirculatory death,
2. A mechanism for determining cardiocirculatory death that is acceptable to the public and HCPs, and
3. An optimal consent-to-donate process.

With this in mind, the following set of ethically informed pragmatic conditions is proposed.

Condition A: Cessation of Cardiocirculatory Function Is Normatively Permanent

For this condition to be met, restoration of the potential donor's cardiocirculatory function by HCPs is not possible due to existing ethical and health law norms. In order for this to be so, an informed decision to permanently withdraw a potential donor's life-sustaining treatment has to be made independent of, and prior to, discussion of possible DCD with the substitute decision maker. The consent process element of relevance to this condition is described in Element 1 of Condition D.

Condition B: The Donor Is Recognized by the Public and Careproviders as Dead

For this condition to be met, enough time needs to elapse between the observed cessation of the donor's cardiocirculatory function and the declaration of death for the status of the donor's body to be recognized by HCPs and members of the public as dead, in the commonly appreciated sense of the word/concept. Educated and media-aware members of the public recognize that an individual's brain is profoundly damaged and no longer capable of meaningful consciousness after about five minutes of not receiving oxygen through spontaneous or artificial blood circulation (in the absence of significant cooling). Given this awareness and the widespread acceptance of the status of brain death as *factual* death, it is likely that many observers, including family members and HCPs, would consider the donor to be dead when his or her body has existed in a non-circulatory state for about this period of time.

Condition C: The Chance of Autoresuscitation Is Exceedingly Remote

For this condition to be met, there needs to be an adequate interval of time between cessation of the donor's cardiocirculatory function and organ procurement to make the chance of autoresuscitation (spontaneous return of cardiocirculatory function after assumed death) "vanishingly small."²⁸ Although empirical data to confirm the accuracy of such an interval is currently lacking, it seems reasonable to consider this interval to be five minutes, based on the previously described, limited clinical experiential knowledge. At least for the time being, this time interval has the advantage of endorsement by the U.S. Institute of Medicine.²⁹ Establishing a minimal interval of this duration would allow for organ procurement to proceed without prior, significant compromise of organ function due to lack of oxygenated blood supply. Although the appropriate minimal interval of time may vary on the basis of future research findings, there is no need for Condition C (itself) to be modified.

Condition D: The Consent Process Is Comprehensive and Optimally Informed

The following is a description of four elements of what the author considers to be an "as *right* as possible" consent process for DCD. Some of these elements contain components of existing DCD practices and are included here to emphasize and reinforce the longitudinal, comprehensive nature of an optionally informed consent process in this context. For the purposes of this account, it is assumed that

the potential donor lacks the necessary capacity to make in-the-moment decisions regarding DCD, as these are the usual clinical circumstances in which controlled DCD is currently actualized in critical care settings. For Condition D to be met, the clinician or clinicians who provide critical care to the potential donor engage in dialogue with the patient's legitimate substitute decision maker (SDM) and ensure that the requirements of all four of the following consent elements have been achieved.

Element 1. Informed Consent for Withdrawal of Life-Sustaining Treatment

The SDM is ethically obliged to make decisions about the maintenance or discontinuation of life-sustaining treatment(s) and intervention(s) in accordance with the known, previously expressed, clear wishes of the capable person (or, in some jurisdictions when these are unknown, in accordance with the known values and beliefs of the patient). When the patient's wishes (and, in some jurisdictions, values and beliefs) are unknown, the SDM is obliged to make these decisions in accordance with what he or she believes to be in the broadly defined best interests of the patient. The timing of this first element of the DCD consent process is crucial—given the previously described potential for conflicts of interest, it must occur before the patient's SDM is approached about the possibility of DCD, that is, it has to occur independently of a subsequent decision to donate organs after cardiocirculatory death.

Element 2. Direct, General Consent to Organ Donation

In the critical care setting, an HCP or HCPs, in possible collaboration with an OD/T coordinator, determine whether the patient has given prior general, affirmative consent to organ donation. This is provided by either a written statement (for example, a donor declaration of a variety of potential sorts) or reliable information provided by another person (for example, a family member) of the patient's prior verbal expression, made while capable, of a clear wish to donate organs at the time of death. This consent element is of importance to DCD because, as described earlier, the details of this particular OD/T practice are essentially unknown to the public, and, as opposed to organ donation after neurological death, DCD involves the performing of pre-mortem investigations and interventions on a living person.

Element 3. Informed Consent for DCD

In relevant critical care circumstances, the SDM is approached about the possibility of DCD after a

decision has been made to withdraw the patient's life-sustaining treatment. In order for the SDM's decision to be reasonably informed, he or she needs to be made aware of the specifics of the DCD practice under consideration, and, in particular, the process/mechanism to be used to determine the patient's death. In the critical care setting, the disclosure of such information is performed by an HCP, in possible collaboration with an OD/T coordinator.

Element 4. Separate Consent for Pre-Mortem Investigations and Interventions

Given the general public's lack of knowledge about the specifics of DCD and the moral relevance of the "live" status of the potential donor from the decision to WLST to the declaration of death in DCD circumstances, separate consent is obtained for the use of pre-mortem investigations and interventions to determine and preserve the viability of the potential donor's organs. In order for the SDM to make an informed decision on behalf of the potential donor, descriptions of the investigations to be used to determine organ viability and the interventions to be utilized to preserve organ viability are provided to the SDM in understandable language. If some of the proposed pre-mortem interventions are not considered necessary for DCD to proceed and/or some are not required for the donation of a chosen, limited set of transplantable organs, the SDM should be informed of his or her option to not provide consent for the use of all the proposed pre-mortem interventions.

SUMMARY COMMENTS REGARDING THE FOUR PROPOSED CONDITIONS

Conditions A to D, as described above, are proposed as a set of ethically informed, pragmatic conditions for potential incorporation into policies that guide DCD practice. Rather than being of a fixed nature, the content of these conditions is designed to be contingent on current clinical evidence and theoretical understandings, and, as such, the conditions are open to iterative revision and enhancement on the basis of new clinical and theoretical developments.

Adoption of the above conditions should not be overly burdensome. The consent process might be slightly lengthened in some circumstances when there is additional discussion about the potential donor's verbally expressed wishes (in the absence of a signed donor certificate) and/or enhanced disclosure to the SDM about the use of pre-mortem investigations and interventions. Although it is pos-

sible that some SDMs will not provide consent to donate their family member's organs on the sole basis of enhanced transparency about the DCD process, there is no empirical evidence to support the prediction of an associated decrease in the rate of organ donation on this basis. If a slight reduction in the number of available, transplantable organs is experienced after adoption of these conditions, this might, in my view, be offset by the benefits of enhanced reassurance of the public and health professionals that the ethical dimensions of this relatively new OD/T practice have received appropriate attention. Such reassurance could potentially generalize to improved public confidence in the ethical integrity of all OD/T practices.

CONCLUSION

Ethical issues and questions of relevance to DCD were briefly explored in this article. Consideration of these provided the foundation for the development of a set of ethically informed pragmatic conditions, the adoption of which could help guide DCD practice. Although interesting and important theoretical disagreements are likely to persist indefinitely in the domain of OD/T, the adoption of ethically informed conditions, the content of which is contingent on current clinical and theoretical knowledge, could potentially assist clinicians "to continue to muddle through" in a "practically unavoidable or even desirable" manner.³⁰

NOTES

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