

# Donation After Cardiac Death: How Best to Address Ethical Concerns

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Post mortem organ donation falls into two broad categories based on the criteria used for the determination of death. When procurement occurs after death determination using neurologic criteria, it is termed "donation after brain death" (DBD). When procurement follows death determined using absence of respiration, circulation, and responsiveness, it is termed "donation after cardiac (or cardiopulmonary, or cardiocirculatory) death, known as DCD.

Donation after brain death is now an accepted form of organ donation, with criteria that have become quite uniform since the landmark Canadian forum on the neurologic determination of death in April 2003.<sup>1</sup>

Non beating heart organ donation or DCD has been gaining in acceptance, and is now practiced in several countries and provides the potential for increased kidney, liver and lung transplantation. Prior to brain death criteria, the historical source of transplantable organs in Canada was from donors after cardiac arrest, without much initial success. While tissue donation (eg. heart valves, cornea, bone) has traditionally occurred after cardiac death in Canada, the acceptance of DCD for solid organ donation has been variable given the circumstances and time constraints related to minimizing ischemic organ injury after cardiac arrest. Despite thorough debate in the literature, a Canadian forum on DCD in 2005 and reviews by the Institute of Medicine, ethical controversies remain concerning the use of non-heart-beating donors. Most relevant to neurocritical care practice is the recommendation to proceed with controlled DCD in Canada, where death is anticipated after a consensual decision to withdraw life support. Two major areas of controversy remain: the definition of irreversible cardiac death, and the ability to clearly identify irreversible illness and make an unbiased decision to withdraw life-sustaining treatments.

Regarding the definition of irreversible cardiac death, the ethics committee of the American College of Critical Care Medicine (ACCCM) has recommended that irreversible cardiac death be defined as a circulation that cannot be restored because CPR will not be applied, with a reasonable observation time of at least two minutes from cessation of cardiopulmonary and neurologic functions with no spontaneous restoration of circulation, but no longer than five minutes. These recommendations are based on limited case reports and small retrospective cohort studies that show, in the absence of CPR, autoresuscitation (spontaneous resumption of cardiac function after cardiac arrest) has not been reported beyond 65 seconds.<sup>2</sup> While large prospective studies are sorely lacking, EKG monitoring after asystole following withdrawal of mechanical ventilation in comatose patients with catastrophic neurologic injury shows that any resumption of cardiac electrical activity is of short duration, consist of bizarre complexes without meaningful contraction and do not produce an arterial pulse.<sup>3</sup>

Although the issue is not resolved in certain centers, clear guidelines are available and accepted, enabling Canadian centers to function with reasonable confidence. The Table provides an example of criteria for death after cardiac arrest recommended for DCD.

Surveys of seriously ill hospitalized patients demonstrate that important elements in end-of-life (EOL) care are trust and confidence in the treating physician, avoidance of unwanted life support, effective and honest communication.<sup>4</sup> In this article we focus on the controversy that is of most concern to neurologists: the way end of life care decisions may be affected by the availability of DCD. Specifically, how accurate is the prediction of survival, how objective and uniform is the decision to withdraw life-sustaining therapy (WSLT), and how uniform and satisfactory is the withdrawal of support.

## Prognosis and the decision to withdraw life-sustaining treatments

One of the principle obstacles to DCD development has been a concern about real and perceived conflicts of interests between providing care for a dying patient and providing the option of donation before death has been established.<sup>5,6</sup>

The fact is that most deaths in neonatal, pediatric and adult

**Table: Representative example of national criteria for the determination of death for DCD<sup>1</sup>**

### Determination of cardiocirculatory death

This forum defined accepted medical practice for the determination of death for the purposes of organ donation in the context of DCD. For the purposes of DCD, we recommend that the following criteria be met before organ procurement:

1. Beginning with the onset of circulatory arrest, there must be a five-minute period during which the absence of palpable pulses, blood pressure and respiration are continuously observed by at least one physician and
2. Death is determined by two physicians by documenting the absence of palpable pulses, blood pressure and respiration on completion of this five-minute period.
3. The physician present during the five-minute period of continuous observation and who makes one of the determinations of death must be a staff physician with the requisite skill and training.
4. Monitoring to establish the fact of death is the priority during this period of observation. There must be no interventions to facilitate donation during this period.

intensive care are related to irrecoverable illness and are preceded by withdrawal and/or withholding of life-sustaining treatment (WLST). This is accepted ICU practice in most countries throughout the world, although there is considerable practice variation. Upon the recognition of medical futility, where the burden of continued treatment far exceeds benefit, WLST takes place after discussion and consent/assent by the patient or the patient's surrogate. Reported WLST rates in single center Canadian ICUs range from 65%<sup>7</sup> to 79%<sup>8</sup> but there is substantial international and geographic variability.<sup>9</sup>

Regardless of the availability of DCD, physicians routinely make predictions of survival and quality of life and have acted upon them to decide upon the withdrawal of life sustaining treatments. Many families will make requests for organ donation under these circumstances, and prior to DCD programs, have been told that organ donation is not an option.

Of course, these predictions are not necessarily accurate. ICU physicians tend to overestimate mortality risk and this influences decision-making at EOL.<sup>10</sup> Physician predictions of a <10% survival for a mechanically ventilated adults compared to an actual 29% survival and was associated with the provision of less intensive care, and a significantly higher odds of withholding or withdrawal of various life support modalities. Physician estimates of a low probability of ICU survival may be more strongly associated with ICU mortality than baseline illness severity, evolving or resolving organ dysfunction, and use of inotropic agents or vasopressors.<sup>10</sup> These studies have been well performed in adult patients with multiorgan failure, but similar high quality studies are lacking for patients with isolated brain injury.

Patient age, disease acuity and cognitive function are the most commonly cited clinical variables impacting on the decision to withdraw or withhold treatments. However, rather than age, severity of the illness or organ dysfunction, the strongest determinants of the withdrawal of ventilation in critically ill adults are physician perceptions that the patient preferred not to use life support, the physician's predictions of a low likelihood of survival in the intensive care unit and a high likelihood of poor cognitive function, and the use of inotropes or vasopressors.<sup>11</sup>

With this in mind, given the already non-standardized way in which physicians make prognoses, could the decision to withdraw life support be influenced by the availability of DCD? If so, how could one guard against this, especially in cases involving neurologic catastrophes?

To alleviate angst and remove bias in the prognostication of patients with catastrophic neurological or neurosurgical illness, one or even two clinical neuroscientists could be consulted. These clinicians would have no role in the care of the patient other than that of prognostication. Objective data could be used in establishing prognosis. Although all the studies suffer from certain methodological inadequacies, they will help with the process of predicting outcome.

In patients resuscitated after cardiac arrest, there are good evidence-based guidelines for prognostication, especially concerning poor prognosis.<sup>12</sup>

The same is true for post-traumatic encephalopathy,<sup>13</sup> and intracerebral hemorrhage.<sup>14,15</sup>

For massive stroke not eligible for craniotomy, the mortality

is shown to be 80%, with severe disability in the 20% who survive.<sup>16</sup>

Subarachnoid hemorrhages also have evidence-based mortality and morbidity according to grade, associated medical complications and the presence of edema.<sup>17-19</sup>

Brainstem strokes where reperfusion is not established can have very high morbidity and mortality, but in this group the decision to withdraw care is much more complex and depends not only on the amount of disability but also the long period of potential recuperation and the conscious, locked-in patient's wishes. For this group, there are no clear evidence-based guidelines despite a known poor prognosis.

All the disorders of neurologic function referred to thus far are conditions capable of causing permanent brain damage, and this is necessary when making a prognostication based on neurologic dysfunction. It would be unwise for the neurologist to offer a prognosis on a patient with septic encephalopathy or other potentially reversible metabolic encephalopathies, regardless of the level of consciousness. These standards can form the basis for prognosis and could be incorporated into a flow sheet that could more reliably predict a permanent outcome no better than severe disability with dependency, in which all basic needs require care givers, in a chronic care facility.

Unfortunately, our ability to accurately define prognosis in severe neurological illness is hampered by the fact that the studies evaluating prognostic indicators have been invariably affected by decisions to limit aggressive care.<sup>20</sup> Controlling for the effect of this confounding factor is extremely difficult, if not impossible. The only reliable way to define prognosis, in ICH and other catastrophic events would be assessing a population in which all patients receive full support, regardless of their perceived probable outcome.

By separating the roles of prognostication from the discussion on WSLT, we can remove some of the bias related to self-fulfilling prophecy.

### Variation in methods of WLST

Another issue that needs to be addressed is the way in which WLST is accomplished. Methods of WLST may vary between individual physicians and ICU centers. There are no standardized procedures for WLST nor is there any intrinsically "correct" way to proceed or optimal duration of the process. Patient care during this phase must be directed to maintaining patient comfort and alleviation of suffering. The principle of double-effect<sup>21</sup> supports the administration of treatments consistent with this intent, even if there is a risk (foreseen but not intended) of hastening death. The use of comfort medications may vary in type (analgesics, sedatives), dosage, and strategy (proactive prevention of pain vs. reactive treatment of pain).<sup>22,23</sup> It is especially important in the process of DCD that there should be no ambiguity that the clinical intention is to relieve suffering of the dying individual in order to maintain public and professional trust.

The existence of practice variations in EOL care, both between and within countries, remains a challenge. This may present a barrier to the establishment of DCD programs or has the capacity to subversively influence DCD practices. Given the known variability in practice, practitioners need to be cognizant about the potential impact of the existence of a DCD program on

the practice patterns of WLST and visa versa. While decisions should best be influenced by patient- and disease-dependent factors rather than physician/hospital characteristics, it is acknowledged that physician characteristics do influence decision-making and prognostication is imperfect.

### **So, how should we deal with these uncertainties?**

The existing imperfections in EOL decision-making do not change the fact that these difficult decisions are continually made. Practitioners and those involved with DCD program development should be cognizant of risks that may lead to erosions of ethical practice. Ethical practice is based on a set of principles that include respect for autonomy, nonmaleficence, beneficence,<sup>4</sup> yet leave room for autonomous reflection.<sup>25,26</sup> The pressures arising from the scarcity of organs and individual or program based donor performance targets linked to funding should be guarded against in order to protect the ethical conduct of practice. These can lead to policy or practice decisions based on what is best for organs, rather than what is best for dying patients. This does not mean that DCD should not take place; it means that specific mechanisms should be in place to guard against inappropriate decisions or conduct. The public strongly supports organ donation and DCD<sup>26</sup> and in many of the recent cases in Canada, DCD has been initiated by persistent family requests.<sup>27</sup> The potential to initiate a DCD program may be a useful impetus to clearly articulate and maintain optimal practices in ICU EOL care.

#### ***1. Patient care issues must be differentiated from those related to organ procurement***

Physicians involved in the ICU patient care and WLST as the patient dies should not be involved also in the care of potential recipients, and transplant physicians must not be involved in the decision to WLST, management of the dying process or in death determination. This minimizes both real and perceived conflicts of interest for ICU staff between their therapeutic duty to the critically ill patient and their non-therapeutic relationship to potential organ transplant recipients.<sup>28,29</sup> Some families might perceive the request for donation to imply that the principal concern of the medical team is with the patient's organs rather than with the patient. It may be appropriate to delegate consent discussions to representatives from an organ procurement organization or to delegate this task to another ICU physician not involved in the care of the patient. The management of the dying process, including procedures for WLST, sedation/analgesia/comfort care should proceed according to existing ICU practice in the best interests of the dying patient. It is the responsibility of the critical care and neurocritical care communities to ensure optimal and safe practice in this field. Respect for the life and dignity of all individuals should remain paramount. The care of the dying patient should not be compromised by the desire to protect organs for donation or expedite death for the benefit of timely organ retrieval. Decisions about care at the end of life should be based on the known values and beliefs of the patient.

Intensivists have been performing this task for decades and should continue to do so, without involvement in the procurement process.

#### ***2. Prognosis should be as accurate as possible and independent of donation potential***

Here is the major area of contention, especially in dealing with neurology/neurosurgery patients. Many intensivists worry about their ability to prognosticate, most specifically in the area of neurological illness. Yet these are the patients most likely to be candidates for DCD. Intensive Care Unit (ICU) physicians have become quite comfortable with the neurological determination of death. Yet many remain uncomfortable when asked to establish a prognosis in the context of potential organ donation, even when there is no clear conflict of interest. The accuracy of the prediction takes on more importance, as the possible bias of potential organ donation on their decision-making becomes a new factor. We would recommend having a consultation with one or two independent neuroscientists well-versed in the method of prognosticating in cases of severe neurological illness to remove some of the uncertainty. Establishing a flow sheet based on the clinical evidence is also recommended.

Indeed, the institution's protocol can stipulate that, when the possibility of organ donation arises in neurological patients, a second physician with relevant experience in neurologic prognostication be brought in for a second opinion. When the main issues are medical, a second physician with experience in medical prognostication is brought in for a second opinion. The physician providing a confirmatory opinion should not be involved with the day-to-day care of the patient or any potential donor.

Certainly there will be variation in practice from one ICU to another and even between individuals in the same ICU, but as long as decisions are being made in the best interest of the patient, the variability should not affect patient care and the possibility of DCD does not change decision-making. Withdrawal of life-support and subsequent organ procurement are permissible provided that the decision to withdraw life-sustaining treatment has been made prior to and separately from the decision to donate organs.

#### ***3. Hospitals should have a standardized approach to WLST***

All acute care hospitals with active ICU's could benefit from a standardized approach to WLST, and this is especially true for centers offering organ donation. In order to minimize "out of bounds" behaviors, there can be a detailed policy and procedure that would clearly articulate their EOL practices and include guidelines regarding withdrawal or maintenance of medication as well as use of analgesics and sedation. Some institutions utilize a pre-donation record sheet as well as a clinical record sheet to make sure that all the details are recorded, including discussion with substitute decision makers.

Trust and confidence in the treating physician may vary according to culture, ranging from collaborative decisions in support of patient autonomy to paternalistic decisions based on physician autonomy and beneficence. Regardless of the ethical foundation, they should be made in the best interests of the patient in care.

#### **Can DCD be accomplished without bias?**

While DCD has generated controversy and diverse opinion, DCD programs have been established in Ontario and Quebec

based on the medical and ethical framework established by the Canadian DCD forum.<sup>30</sup> It is our view that DCD can be accomplished without bias as long as certain safeguards are in place. Decisions as to the irreversibility of the underlying illness will remain imprecise, as none of us is capable of prognosticating to 100% exactitude. However, by simply continuing standard practice, by involving an outside physician well versed in neurological prognostication, and by avoiding all involvement in the transplant process, the intensivist will be able to act in the best interest of his or her patient.

Withdrawal of life support can be done and is already done by intensivists and Neurologists around the world in a dignified and timely manner. With the advent of DCD, the management of the dying process should continue according to existing ICU practice in the best interests of the dying patient. While it is the responsibility of the critical care and neurocritical care communities to ensure optimal and safe practice in this field, research is ongoing in this regard. In the context of DCD, the aforementioned variability in WLST practice calls for improved guidelines in order to facilitate uniform decision making to assist the caregivers and provide the ability to audit performance.

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