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J Intensive Care Med 2008; 23; 303 originally published online Jul 22, 2008;
DOI: 10.1177/0885066608320928

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Organ Procurement After Cardiocirculatory Death: A Critical Analysis

Mohamed Y. Rady, MD, PhD, Joseph L. Verheijde, PhD, MBA,
and Joan McGregor, PhD

To shorten the transplantation waiting time in the United States, federal regulations have been introduced requiring hospitals to develop policies for organ donation after cardiac (or circulatory) death (DCD). The practice of DCD is invoked based on the validity of the University of Pittsburgh Medical Center (UPMC) protocol and relies on the accuracy of the University of Wisconsin (UW) evaluation tool to appropriately identify organ donors. There is little evidence to support the position that the criteria for organ procurement adopted from the UPMC protocol complies with the dead donor rule. A high false-positive rate of the UW evaluation tool can expose many dying patients to unnecessary perimortem interventions because of donation failure. The medications and/or interventions for the sole purpose of maintaining organ

viability can have unintended negative consequences on the timing and quality of end-of-life care offered to organ donors. It is essential to address and manage the evolving conflict between optimal end-of-life care and the necessary sacrifices for the procurement of transplantable organs from the terminally ill. The recipients of marginal organs recovered from DCD can also suffer higher mortality and morbidity than recipients of other types of donated organs. Finally, transparent disclosure to the public of the risks involved to both organ donors and recipients may contribute to open societal debate on the ethical acceptability of DCD.

Keywords: cardiocirculatory death; ethics; organ donation; organ procurement; transplantation

Transplantation medicine has evolved to include both living and deceased organ donation for successful treatment of end-stage organ disease (eg, kidney, liver, pancreas, heart, and lungs). Recent expansion of organ transplantation has changed the demographics and pattern of end-stage organ disease, thus vastly increasing the number of potential organ recipients on the waiting list.^{1,2} The disparity between the supply and demand for organs is predicted to grow over the next decade in the United States.³⁻⁵

To address the evolving organ shortage, federal and health regulatory agencies, in collaboration with the transplantation community, introduced the requirement for implementation of hospital policies for organ donation after cardiac death (DCD)—also known as non-heart-beating, circulatory death, or imminent death organ donation—across hospitals in the United States.⁶⁻¹⁰ DCD was reintroduced to

increase the supply of organs for demands not met by brain death and living organ donation. DCD includes organ donation from individuals who are neurologically intact before elective removal of life support and sudden in-hospital or out-of-hospital cardiac arrest.⁹ The reintroduction of DCD practice is based on the University of Pittsburgh Medical Center (UPMC) protocol and the University of Wisconsin (UW) evaluation tool.⁹ The UW evaluation tool is used to select potential candidates for organ donation. In 2007, the United Network for Organ Sharing (UNOS)—a private organization that has regulatory oversight of organ procurement and allocation and coordinates US organ transplant activities—approved new bylaws for DCD recovery protocol model elements.¹¹ This article evaluates the evidence for the UPMC protocol and the UW evaluation tool and explores the ethical ramifications of their application to DCD.

The UPMC Protocol

The UPMC constituted a protocol to allow organ procurement from DCD in 1992. This protocol was developed in response to the desire from patients and families to donate organs from unsalvageable patients not meeting formal brain death criteria before death.¹² The UPMC protocol states that organs may be procured if the patient or the family requested organ donation after the decision to withdraw life support (ie, withdrawal of mechanical ventilation and/or hemodynamic circulatory support) and the forgoing of resuscitative interventions. The protocol allows organ procurement from patients when they meet specific criteria for cardiorespiratory death following the elective withdrawal of life support. Patients are moved to the operating room for preprocurement interventions before the withdrawal of life support. Patients are monitored until cardiorespiratory death is pronounced. Surgical recovery of donated organs begins after the pronouncement of death and a variable time to ensure no unexpected autoresuscitation. To obtain transplantable organs in the UPMC protocol, the warm ischemia time (waiting time between withdrawal of life support and recovery of organs) must be as short as possible. In the original UPMC protocol, cardiorespiratory death is pronounced after 2 minutes of simultaneous apnea, unconsciousness, and pulselessness confirmed by a femoral arterial catheter irrespective of the presence or absence of electrocardiographic cardiac activity, that is, pulseless electric activity (formerly electromechanical dissociation) or ventricular fibrillation.

The UW Evaluation Tool

Critical to the successful execution of the UPMC protocol is the ability to predict the time of death after planned withdrawal of life support. The UW developed

an evaluation tool to predict the time of death and therefore determine the suitability of organ donors for DCD.¹³ The UW evaluation tool determines the probability of cardiorespiratory death within 90 minutes after withdrawal of life support. The UW considers organs procured after 90 minutes not suitable for transplantation because of warm ischemia. Other transplant centers have rejected organs for transplantation with warm ischemia time longer than 30 minutes. The UW evaluation tool requires the measurement of respiratory parameters and vital signs (eg, respiratory rate, tidal volume, negative inspiratory force, pulse, blood pressure, and oxygen saturation) after temporary disconnection from the ventilator for a 10-minute trial of spontaneous respiration through an endotracheal tube or a tracheostomy. A UW score is calculated from the measured variables, with additional scores for age, use of vasopressors, and type of intubation. High UW scores indicate an increased likelihood for death within 90 minutes after extubation and thus a higher suitability for the UPMC protocol.¹³

Scientific Validity of the DCD Practice

The DCD practice and the validity of the UPMC protocol and UW evaluation tool have been the subject of intense ethical and scientific debate.¹⁴ The UPMC protocol uses an arbitrary set of cardiorespiratory criteria defining death for the purpose of recovering transplantable organs. The assumption has been that, without resuscitative interventions, the heart will be irreversibly stopped after 2 minutes of pulselessness such that it cannot restart on its own and that this precludes spontaneous return of circulation and cerebral perfusion (autoresuscitation or Lazarus phenomenon) during the procurement process. The 2-minute period of pulselessness ignores the presence of electric cardiac activity on the electrocardiogram. The principal scientific evidence for the *irreversibility* of cardiorespiratory cessation at 2 minutes is based on DeVita's

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There are no affiliations or financial involvement with any organization or entity with a direct financial interest in the subject matter or materials discussed in the manuscript. The authors declare that they have no competing interests.

All the authors (1) have made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and (3) have given final approval of the version to be published. Each author has participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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review of published case reports on 108 patients between 1912 and 1970 who died during the monitoring of vital signs before and after death.¹⁵ DeVita concluded that there is no evidence that humans have spontaneously recovered circulation after 65 seconds when an absence of circulation has been verified and cardiopulmonary resuscitation is not attempted. DeVita reported his own observations on the cessation of vital signs and cardiorespiratory functions in patients allowed to die after withdrawal of life support, albeit without simultaneous monitoring of brain stem electric activity and/or function before and during organ procurement.¹⁶ The observations on signs of cardiac and neurologic functions and activities were discontinued when the procurement process was started. On the basis of DeVita's death criteria, the Institute of Medicine and Society of Critical Care Medicine quickly endorsed the UPMC protocol with a slight modification to extend the waiting time to 5 minutes (instead of a 2 minutes) of simultaneous apnea, unconsciousness, and pulselessness before beginning surgical removal of donated organs.^{17,18} The UPMC protocol continued to use a 2-minute waiting period, while different institutions developed their own protocols without consistency or uniformity of waiting times (range, 2 to 5 minutes) for the declaration of death before procurement.^{19,20} The Institute of Medicine remained silent about the scientific, ethical, and legal doubts of the death criteria for organ procurement in DCD.²¹ It is also critical that the UPMC and the Institute of Medicine criteria for organ procurement comply with the legal standard and the statutory definition of death. The US law forbids the removal of vital organs for donation until the donor is declared dead, otherwise, such an act shall be considered homicide.²²

The main ethical concern about DCD has revolved around the question of whether circulatory arrest for 5 minutes is sufficient to comply with the irreversibility of the Uniform Determination of Death Act (UDDA) of 1981, which defined death as either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem. When the UDDA (1981) was drafted, the irreversibility requirement for the loss of circulation in defining death was explicitly described in the final report.²³ The President's Commission emphasized that death is a single phenomenon so that neurologic criteria must be fulfilled when cardiorespiratory criteria are used for a determination of death. The President's Commission considered

that a minimum of 10 to 15 minutes of circulatory arrest is necessary for neurologic death; nevertheless, they also specified that "a determination of death must be made in accordance with accepted medical standards."²³ The President's Commission envisioned that "accepted medical standards" changed with time because of continued advances in the field of resuscitation of refractory circulatory arrest with cerebral neuroprotection and better diagnostic tools for verifying cessation of brain function and activity. The President's Commission requires that such advances in therapeutic and diagnostic technology to be incorporated in the process of determining death. Therefore, it is feasible that 20 to 60 minutes of refractory circulatory arrest, for example, with hypothermia, can retain sufficient brain viability for full neurologic recovery.^{24,25} The only time that death is certain is when cessation of function is fully delineated and irreversibility has been established with confidence using the prevailing technology at that time.²⁰

Since 1981, scientific evidence has accumulated to prove that 5 minutes of circulatory arrest is too short to verify death to begin organ procurement and still comply with the dead donor rule in DCD. Pulseless electrical cardiac activity on the electrocardiogram (which is ignored during organ procurement) can be associated with mechanical contractions too weak to be detected by pressure monitoring.²⁶ Autoresuscitation has been documented in the medical literature after more than 10 minutes of circulatory arrest and discontinuation of resuscitation in humans.²⁷⁻³⁰

The application of an arbitrary time for circulatory arrest alone does not comply with the dead donor rule when artificial circulation is initiated upon declaration of death for in situ organ perfusion during the procurement process.^{31,32} In 2007, UNOS included extracorporeal membrane oxygenation (ECMO) and bronchoscopy as donation-related procedures in DCD.¹¹ Artificial support of circulation with cardiopulmonary bypass and reintubation for lung ventilation are required for organ viability in donors. The donation-related procedures can resuscitate (reanimate) organ donors during procurement, which requires pharmacological agents (chlorpromazine and lidocaine) and/or occlusion of coronary and cerebral circulation for suppression.^{31,33,34} In fact, DeVita agreed that brain function can recover if resuscitation is attempted within 11 minutes after circulatory and respiratory arrest.¹⁵ Other studies confirmed the effectiveness of ECMO and cardiopulmonary bypass for the return of full neurologic

function after prolonged refractory circulatory arrest.^{35,36} The above observations attest to the resilience of the human brain, including the brainstem, to irreversible cessation of function after short periods of 2 to 5 minutes of circulatory arrest. This is particularly troubling because UNOS bylaws include patients with end-stage musculoskeletal disease or pulmonary disease with normal neurological function as candidates for DCD.¹¹ Patients with end-stage congestive heart failure supported with mechanical ventricular assist devices and who are not transplant candidates are also included after consent as DCD when the devices are turned off.³⁷ Under such circumstance, organ donors may retain residual brain stem, if not higher cerebral, function or activity during procurement-related procedures after 2 to 5 minutes of circulatory arrest.

Some authors advocate that neurological and cardiorespiratory criteria must be applied simultaneously to sharpen the indeterminate boundary between life and death.³⁸⁻⁴¹ The simultaneous application of dual criteria for the determination of death has increasingly become relevant because of the acceptance of advanced artificial circulatory technology for organ resuscitation until completion of procurement.^{11,42,43} Artificial circulation should not be initiated until death is declared after circulatory arrest long enough to ensure the irreversible cessation of brain stem function upon reperfusion of the donor brain during the procurement process.^{35,36,44}

Like the UPMC protocol, the UW evaluation tool also generates concerns about its scientific validity and applicability. The report of a national conference recommends the clinical use of the UW evaluation tool.⁹ The inaccuracy of prediction of the time between withdrawal of life support and declaration of death can harm prospective organ donors. Donation failure will ensue if prospective organ donors survive longer than anticipated after withdrawal of life support. If donation failure occurs, nonbeneficial perimortem interventions have already been performed to ensure organ viability before the withdrawal of life support. Donation failure from inaccurate prediction of the time of death also increases the risk of prolonged warm ischemia time and makes procured organs unsuitable for transplantation.

There are other problems with the UW evaluation tool. First, the study sample for the development and validation of the tool was small (43 patients). All patients had severe irreversible brain

injury (Glasgow coma score <5), and all were being evaluated for brain death as well as being considered at risk of imminent neurologic or brainstem death. The UW evaluation tool has unjustifiably been assumed to apply to other types of patients for whom the determination of DCD suitability must be made.¹¹ These patients may be neurologically intact and have terminal diseases that are distinct from the cohort included in the UW study.¹³

Second, the Wisconsin study does not define the criteria for time of death either by cardiac electric rhythm (ie, ventricular fibrillation, electric asystole, or pulseless electric activity) or pulselessness and the duration of either or both. Not having a consensus definition or agreement on the criteria to precisely define the time of death casts doubts on how accurately the UW evaluation tool can determine survival time (error margin for estimation measured in minutes) after discontinuation of ventilatory and hemodynamic support.

Third, the measured respiratory parameters and vital signs for calculating the UW score can fluctuate in different respiratory patterns (eg, Kussmaul and Cheyne-Stokes) in patients undergoing withdrawal of ventilatory and hemodynamic support. The failure to address respiratory variations can lead to erroneous calculation of scores and misclassification by the UW evaluation tool. The UW evaluation tool does not address the variability of the cardiocirculatory or hemodynamic patterns seen during the natural dying process after withdrawal of ventilatory and hemodynamic support.^{45,46} The UW evaluation tool has been criticized because of its potential for a high false-positive rate and poor specificity for identifying suitable DCD candidates in general ICU patients. A high false-positive rate of the UW evaluation tool can expose many dying patients to unsuccessful enrollment in DCD and perhaps inflict unnecessary distress on health care providers and families because of donation failure.⁴⁷ Donation failure has been reported in at least 20% of patients enrolled in DCD.⁴⁸

Withdrawal of Life Support in the ICU

There is a misconception that withdrawal of ventilatory and hemodynamic support will result in immediate or imminent death in the ICU. A survey of withdrawal of mechanical ventilation in the critically ill adults at 15 ICUs found that 21 of 166 patients (13%) survived to ICU discharge after withdrawal of life support.⁴⁹ The

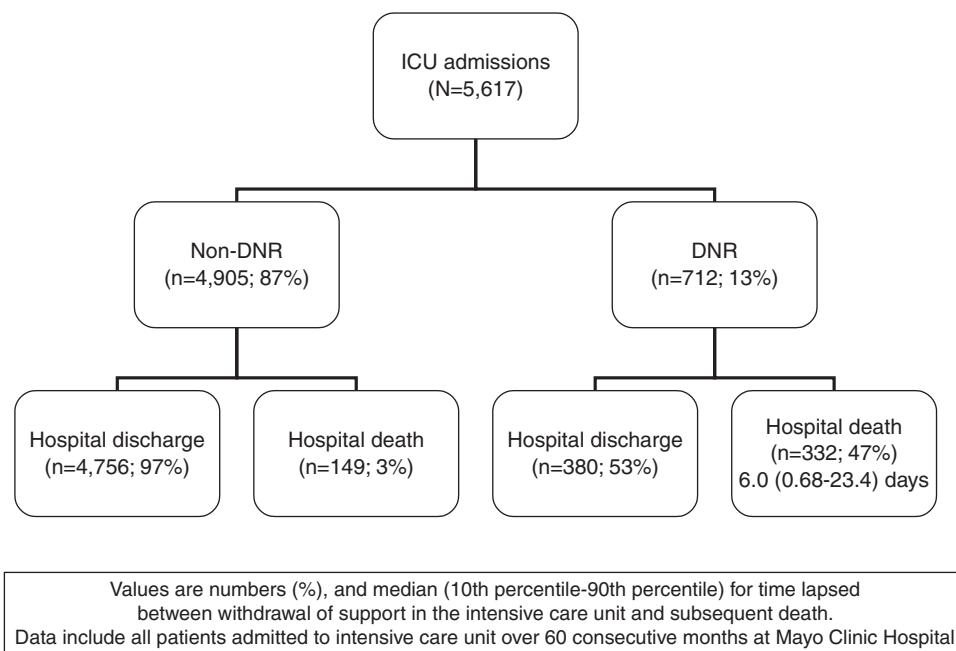


Figure 1. Of 5,617 admissions to intensive care units (ICUs) at Mayo Clinic Hospital, Phoenix, Arizona, during a 60-month period (between January 1, 1999, and December 31, 2004), 712 resulted in do-not-attempt-resuscitation (DNR) orders and withdrawal of life support. Of the patients with DNR orders, 53% were discharged from the hospital and 47% died while in the hospital. For patients who died in the hospital, the time after withdrawal of support until death is shown as the median (10th to 90th percentile).

median time to death for ICU patients who can be considered DCD candidates has been reported at 4.8 hours (Inter-quartile range 1.4-11.5) after withdrawal of life support.⁴⁵ That time interval exceeds the maximum tolerable warm ischemia time of 90 minutes for organ procurement. At Mayo Clinic Hospital, Phoenix, Arizona, ICU patients admitted between January 1, 1999, and December 31, 2004 had a 53% survival rate to discharge after withdrawal of life support (Figure 1). Patients who died in the hospital did so after a median (10th to 90th percentile) of 6 days (0.68-23.4 days). In a study of withdrawal of life support in the ICU after initial successful resuscitation of out-of-hospital cardiac arrest, 29 out of 57 (51%) patients died after >120 minutes.⁴⁶

It has also been suggested that the variability of time lapse between withdrawal of life support and death can be influenced by the timing of do-not-resuscitate (DNR) orders among different institutions. Institutional characteristics such as large size, academic standing, for-profit status, and availability of specialty physicians are associated with delaying DNR orders even after adjusting for differences in patient and disease

characteristics.⁵⁰ Timing of DNR orders and withdrawal of life support until death is imminent may constitute conflicting interests for academic institutions with strong reputations for transplantation and organ procurement programs.

Institutional Conflict of Interest

The need for surgical recovery of transplantable organs can influence the selection of certain subsets of potential donors to optimize the expansion and success of transplantation programs within interested institutions.⁵¹ The mere presence of other motives in transplantation practice introduces the risk of laxness in the regulation of protocols and conflict of interests in the field of organ donation to the detriment of acceptable standards for patient care.⁵²⁻⁵⁴ Institutional protocols for DCD have explicit safeguards excluding the presence of the transplant or procurement professionals prior to the declaration of death in organ donors. Nevertheless, the same safeguards fail to prevent the dual and

conflicting roles of the critical care and transplant or procurement professionals. These safeguards also fail to differentiate between patient care versus donor care in the ICU.⁵⁵ In circumstances involving possible organ donation, it can be difficult not to manage patients as potential donors rather than as dying patients.⁵⁶ Some institutions have permitted onsite in-house coordinators from procurement organizations to engage in donor surveillance and management in the ICU before donation consent and without families' knowledge to increase donation rate.⁵⁶ Because of the financial interests of health care and health care-related industries,⁵⁷ the institutional ethos in established transplant centers become subordinate to transplantation practice, which can introduce the risk of unconscious identification with the program. That in itself can create a situation of policy creep: Under the right social or psychological pressure, committing the morally justifiable "A" prepares us psychologically to accept the morally, albeit logically distinct, more questionable "B."

DCD and End-of-Life Care

The goal of palliative care is a "good death" free of avoidable distress and suffering in accordance with clinical, cultural, and ethical standards and the wishes of patients and their families.⁵⁸ The quality of end-of-life (EOL) care for hospitalized dying patients has increasingly come under public scrutiny and criticism.⁵⁹ A Robert Wood Johnson Foundation survey reported that the majority of hospitalized patients do not have access to appropriate palliative or hospice care programs at the EOL.⁵⁹ Striking variations have also been reported among academic hospitals within the United States for provision of appropriate EOL care during the last 6 months of life.⁶⁰ The report indicated that ICU admission before death for life support therapy is a common substitute for palliative or hospice care at the EOL at academic hospitals. Institutional resources (eg, bed availability and medical subspecialties, including transplantation) rather than disease status and patient preferences dictate the type of medical care offered at the EOL.⁶⁰ Institutions with a successful transplantation and/or organ procurement program are no exception to these reported observations about EOL care.

The observation of a wide variation in DNR timing among institutions appears to validate the theoretical concern that institutional practice-related factors

(other than patient characteristics, disease, and preferences) preferentially dictate the utilization of life support therapy over palliative care at the EOL.⁵⁰ This poses the following question: Will the implementation of DCD in hospitals widen the current gap in delivery of compassionate EOL care to the terminally ill? Unwarranted initiation or prolongation of life support until death is imminent may be considered in order to determine the suitability for DCD. The 2006 revision of the Uniform Anatomical Gift Act requires, once life support interventions have been initiated, that they not be withheld or withdrawn until the patient has been examined and evaluated by procurement personnel for potential organ donation.²² Many organ procurement organizations implement additional treatment pathways for potential DCD candidates to maintain organ viability prior to procurement.^{11,61} Withdrawal of life support may be delayed either until the brain-death criteria are fulfilled (to harvest the heart in addition to other solid organs) or until cardiorespiratory functions have deteriorated such that death will quickly ensue upon withdrawal of life support. Both practices can have negative consequences on the timing and quality of palliation and EOL care offered to prospective organ donors.²⁸

The need to procure viable organs can undermine the type and quality of EOL care offered to prospective organ donors.⁶¹⁻⁶³ DCD requires the transfer of patients before or upon death to the operating room for organ procurement. Opioids and sedatives may be withheld to avoid hastening death before withdrawal of life support and completion of preparation for organ procurement.⁵² Another concern has also been expressed that upon withdrawal of life support, excessive doses of opioids and sedatives may be administered for early onset apnea and pulselessness to shorten the warm ischemia time for organ procurement.⁴⁸ Likewise, the administration of heparin to prevent the formation of blood clots in the solid organs of a potential organ donor may precipitate internal hemorrhage and hasten the donor's death.⁶⁴ The administration of vasodilators to promote solid organ perfusion can exacerbate hypotension and the onset of cardiocirculatory arrest on withdrawal of life support.⁶²

Respect for cultural and social diversity of behavior surrounding death is an important element of EOL care and for grieving families.⁶⁵ For example, allowing the patient's family members adequate time alone with the patient immediately after death and providing dignified bedside scenes are supportive

ways to improve EOL care for ICU decedents and their families.^{65,66} Yet, the logistics of organ procurement immediately on death preclude such pivotal supportive behavior that may lessen the bereavement burden for families. It is necessary to address and manage the evolving conflict between optimal EOL care and the necessary sacrifices for the procurement of transplantable organs from the terminally ill.^{28,63}

Transplantation Outcome of Procured Organs

DCD has been proposed as a solution to fulfill familial requests to increase the supply of organs and shorten transplantation waiting lists. Although timely organ transplantation can save lives, organs of marginal quality procured from the deceased can also increase organ recipients' morbidity and mortality. Organs procured from DCD donors tend to be of inferior quality compared to living or brain death donation.^{67,68} Data from a US national registry of mortality and graft outcomes among kidney transplant candidates and recipients (109,127 patients) were used to examine the 3-year relative risk of mortality for recipients of marginal kidneys versus those receiving hemodialysis on the waiting list.⁶⁹ The mortality of recipients of marginal kidneys from the deceased was much higher than that of patients remaining on hemodialysis for the ensuing 3 years.⁶⁹ Marginal kidneys were recovered from deceased donors older than the age of 50 years with a history of hypertension and a cerebrovascular cause of death. Recipients of marginal kidneys have high mortality because of complications related to immunosuppression treatment as well as premature graft loss and subsequent reinitiation of hemodialysis.⁷⁰ Based on national data from the Scientific Registry of Kidney Transplant Recipients (175,436 patients), the mortality among patients on dialysis therapy after primary graft failure increased significantly relative to mortality among patients still awaiting primary kidney transplantation.⁷⁰ Kidney transplant recipients with high risk for cardiovascular disease also sustained high posttransplant morbidity and mortality because of increased incidence of cardiac events.⁷¹

Data from the Scientific Registry of Liver Transplant Recipients (24,070 transplants) have also reported higher incidence of graft failure and

subsequent morbidity and mortality of recipients of DCD livers when compared with those recipients of livers procured after brain death.⁶⁷ It appears that DCD livers are associated with a significantly increased risk of graft failure unrelated to modifiable donor or recipient factors. In an analysis of deceased donor liver transplant recipients (24,688) from the UNOS database, the 3-year patient and graft survival of recipients of DCD livers was also reported to be inferior to that of recipients of livers donated after brain death.⁷² Poor graft function can negatively influence the long-term recovery of liver transplant recipients' health and quality of life.⁷³ If the transplantation of marginal organs from the deceased has a worse outcome for the recipients, then the implementation of DCD recovery program will most likely increase the supply of poor-quality organs and paradoxically lengthen the waiting lists because of the high rate of graft failures and demand for retransplantation. Indeed, the numbers of retransplant candidates on the waiting list have grown most notably in kidney transplantation because of graft loss faced by transplant recipients.⁷⁴ Unfortunately, the risk of graft failure following retransplantation is significantly higher than that observed for primary transplants. More studies are needed to quantify and inform organ recipients of the risk involved with the transplantation of marginal organs procured from the deceased of either brain death or DCD.

Conclusion

There is little evidence to support that the DCD practice complies with the dead donor rule. The likely high false-positive rate of the UW evaluation tool can expose many dying patients to unnecessary perimortem interventions. The use of medications and/or interventions for the sole purpose of making the organs more viable can have unintended negative consequences on the timing and quality of organ donors' EOL care. Recipients of marginal organs from DCD may suffer higher mortality and morbidity than recipients of other types of donated organs. Transparent disclosure to the general public of the risks involved to both organ donors and recipients is essential for societal debate on the ethical acceptability of DCD. Additional studies independent of UNOS for critical analysis of the cost-benefit of DCD are required to determine if that practice best serves the general public interest.

Addendum

Since manuscript acceptance, a federally funded study of established UNOS donor identification criteria was completed to predict cardiorespiratory arrest within 60 minutes after withdrawing life support and determining DCD suitability.⁷⁵ By UNOS donor identification criteria, the study reported an 18% to 71% donation failure rate in DCD patients. The study did not address temporal characteristics of auto-resuscitation in DCD.

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