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Donation after Cardiac Death

A report from the
Subcommittee on Donation after Cardiac Death

Of the
Bioethics Committee
Contra Costa Regional Medical Center & Clinics

Submitted to the Medical Executive Committee and the Executive Director of the Hospital and Clinics

September 2006
This document reports the findings and recommendations of the ad hoc Subcommittee only. This Subcommittee is strictly advisory. The content of this document does not represent the opinions or policy of Contra Costa Regional Medical Center, its Medical Staff, Administration, or governing Board.

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* Ms. Dawes was unable to participate in the later stages of our process, including final deliberations.
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Executive Summary

A little more than one year ago, CCRMC performed its first case of organ donation after cardiac death (DCD). A disturbed young man tried to hang himself in his jail cell. He did not die, but was admitted to the ICU with severe anoxic brain injury. Ten days later, and with the consent of his family, the patient was taken to the operating room where ventilatory life-support was discontinued. The patient sustained cardiac arrest and, immediately after the pronouncement of death, a surgical team entered the operating suite and removed his organs for donation.

In the wake of ethical issues raised by this case, the Bioethics Committee formed an interdisciplinary ad hoc subcommittee to study the DCD procedure and to formulate recommendations for the Medical Executive Committee and Administration with respect to future DCD policy and procedures at CCRMC. This document summarizes the process, findings, and conclusions of that group.

The Subcommittee first reviewed the history of DCD in the context of emerging transplantation technology and evolving definitions of death. The earliest cases of cadaveric organ donation relied upon organs taken from the recently deceased – that is, individuals whose hearts had stopped beating. Unfortunately, the organs obtained from these first DCD cases were often of very poor quality due to the delay required to assemble a surgical team for procurement. With the legal codification of a dual definition of death by either cardiorespiratory (irreversible cessation of circulatory and respiratory function) or neurologic criteria (irreversible cessation of all functions of the entire brain, including the brain stem), a whole new source of organs for transplantation was identified. Organs obtained from this new group of well-perfused “brain dead” patients were far superior to those coming from donors who suffered cardiac death. And so, donation after brain death (DBD) almost completely replaced DCD in this country.

Under the pressures of a large and ever-growing “organ gap” between the number of candidates on transplantation waiting lists and the number of organs available, there have been efforts to identify sources beyond the limited pool of brain dead donors. This has led to renewed interest in DCD as a potential major contribution to national procurement strategies. But DCD today can, for many cases, be very different from the cases of years ago. It can now be “controlled”. Since the early days of transplantation, an ethical, social, and legal consensus had emerged supporting the right of patients or their surrogates to choose withdrawal of life-support technology. This means that it is now possible to anticipate and plan for a patient’s death by cardio-respiratory criteria following the choice to withdraw life-support technology. The organs obtained by this controlled DCD process (excluding the heart) are of a much higher quality than those available through an uncontrolled cardiac death – approaching the utility of organs from brain dead donors.

The Subcommittee viewed the actual DCD process in terms of a number of critical elements – each step with attendant ethical issues. Taken together, these elements describe a rough chronological
flow through the DCD protocol.

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The Subcommittee next considered the ethical arguments – both “pro” and “con” – surrounding the DCD controversy. Supporters argue that the ethical foundation for implementation of DCD protocols does not represent new ethical ground, but is a logical extrapolation of established rights. Specifically:

The right to withdraw life-support
+ The right to donate organs = The right to DCD

Furthermore, DCD is justified by a number of arguments that reflect our common values:

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Critics of DCD challenge the deductive logic presented above. This calculus of rights is, they argue, overly simplistic. The process of DCD actually changes the moral landscape of the clinical scene. It requires careful reconsideration rather than reliance on pre-existing norms that never imagined DCD. Such reconsideration raises the following ethical concerns:
Arguments in Opposition to DCD

| Conflicts-of-interest and decreases trust | Counters progress in end-of-life care |
| Manipulates definition of death | Ignores social justice issues (uninsured) |
| Violates “do no harm” | Lacks social consensus (bad process) |
| Weak informed consent | May decrease donations |
| Slippery slope | Feels intuitively wrong |

It was apparent to all members of the Subcommittee that any responsible implementation of DCD would require a carefully crafted structure of limits and protections. To explore the possibility of writing such a policy that could protect against identified ethical concerns, the group engaged a thought experiment. This exercise asked that all members of the Subcommittee accept the false premise that we must write a policy permissive of DCD. This allowed us to envision the practical implications of some of the theoretical issues and to see whether we could reach a consensus around a policy. Having envisioned what a DCD-permissive policy might look like, the group next considered what a non-participation policy might involve.

No single line of reasoning emerged from the Subcommittee’s deliberations. Each member had a unique perspective on the various ethical dimensions of DCD. A number of generalizations, however, can be drawn. The opportunity to honor patient and family wishes for donation and the potential to save lives were clearly the most compelling arguments in support of DCD. And, though there was a wider range of opinion for positions in opposition to DCD, the most compelling “con” arguments involved concern that DCD poses conflicts-of-interest, compromises trust, and has been pushed by the transplantation community without achieving a social consensus.

All Subcommittee members could agree on a number of conclusions:

- DCD is ethically complex. Reasonable people can disagree on this topic.
- There are strong ethical arguments favoring implementation of DCD — especially the potential to save lives and the opportunity to honor the wishes of the patient or family.
- The linear, deductive argument based on “rights” is not sufficient, on its own, to sustain the case for DCD.
- The clinician’s primary responsibility must remain to the patient.
- The national process for DCD approval and implementation has been inadequate to date.
- Lack of broader community buy-in runs the risk of exacerbating distrust of medicine, with resulting paradoxical reduction in donor rates.

Where we could not find consensus, disagreement arose from our individual assessments of:

- The degree to which ethical ambiguities and tensions should be tolerated to secure the clear and substantial benefits of DCD;
- The degree to which procedural safeguards of a written policy can adequately protect against potential problems; and
- The degree to which weaknesses in the process for DCD approval and implementation at this point dictate a position of non-participation.

In the end, nine members voted for a policy of non-participation with DCD, while two members felt that a carefully crafted policy and protocol should be adopted.

The Subcommittee on Donation after Cardiac Death submits the following recommendations to the CCRMC Medical Executive Committee and to Administration:

1. Do not implement DCD procedures at CCRMC.

2. Adopt a policy (detailed on page 31) that does not permit DCD at CCRMC, but allows for transfer of a patient to another area facility for purposes of pursuing a DCD procedure – if requested by the patient or surrogate.

3. Present this report to the Professional Affairs Committee or other appropriate oversight body.

4. Work with the OPO to maximize identification and appropriate management of candidates for organ donation after brain death and for other tissue donations.

5. Facilitate donor registry amongst staff and patients.

6. Participate in public discussion of DCD. Such participation should include advocacy for just allocation of transplantation resources irrespective of the individual patient’s ability to pay.

7. Identify a member of the professional staff to serve as CCRMC Organ and Tissue Donation Coordinator.

8. Remain open to change.

All members of the Subcommittee affirmed that the processes of discovery and deliberation were thorough and fair, and accepted the above consensus recommendations.
Introduction

In August of 2005, a young man was found unconscious in his cell at the county jail with a sheet tied around his neck in an apparent suicide attempt. He was cyanotic, apneic, and pulseless at the scene, but resuscitative efforts restored a pulse and blood pressure. The patient, Mr. C, remained comatose, and neurologic evaluation was consistent with severe anoxic brain injury, including some evidence of damage at the brain stem level. After discussion with his physicians, the family thought it would be best to discontinue life-support treatments and allow the patient to die. However, they also hoped that it might be possible to donate his organs following his death. And so, Mr. C remained on full life-support with the expectation that he would soon meet brain death criteria – and his organs could be procured.

In the ensuing days, the patient showed no improvement, but neither did he “progress” to meet neurologic criteria for death. The local Organ Procurement Organization representative informed the family and medical team that donation could still be accomplished, even in the absence of brain death. The medical team was not familiar with this proposed procedure, but recognized it as substantively different from standard donation following brain death. The OPO representative provided reassurance that this approach was ethically appropriate. Nonetheless, the attending physician contacted a member of the Ethics Committee for advice. Over the ensuing few days, discussions were held covering a range of ethical aspects of the case, including autonomy, beneficence, avoidance of coercion, and the use of palliative medications during withdrawal of care. In the course of these discussions, a number of staff – including senior nurse supervisors, the Chief of Anesthesiology, and others – expressed serious ethical reservations. Finally, a decision was made to honor the family’s strong desire for organ donation and proceed with withdrawal of life-support, followed by organ procurement after cardiac death.

Ten days following his injury, the patient was taken to the operating room, still on full life-support. A surgical organ recovery team waited outside the OR doors. Inside, the medical team extubated the patient and discontinued all supportive therapy. Within 20 minutes, the patient stopped breathing, his heart stopped, and he was pronounced dead. The surgical team immediately entered the suite and excised the patient’s vital organs. Three recipients benefited from the organs procured from Mr. C. This was the first case of donation after cardiac death (DCD) performed at CCRMC.

Our Bioethics Committee reviewed this case at its September 2005 meeting. At that discussion, a number of difficult ethical issues associated with the DCD approach were identified. An interdisciplinary ad hoc subcommittee (hereafter referred to as the “DCD Subcommittee”) was formed to study the ethical dimensions of organ donation after cardiac death, and to formulate recommendations for the Medical Executive Committee and Administration with respect to DCD policy and procedures at CCRMC. After its first meeting in October 2005, the DCD Subcommittee recommended a moratorium on further DCD procedures at this facility, pending further consideration and possible formulation of a protocol. The moratorium was approved by the MEC.
and remains in effect at this time. This document summarizes the process, findings, and recommendations of the DCD Subcommittee.

It should be noted that the Subcommittee did not undertake an analysis of organ donation policies generally. We did not question whether transplantation is the most prudent strategy for maximizing health benefits to our society. Nor did we attempt to assess the advisability of DCD relative to other possible national approaches to closing the organ gap. Thus, we did not evaluate the ethical benefits and burdens of DCD as compared to other proposals – such as mandated choice, presumed consent, or financial incentives. And, though our study considered many aspects of DCD, we limited our discussion to DCD in the “controlled” setting – that is, situations in which cardiac arrest can be anticipated and a transplant team brought to stand by for rapid procurement at the moment of death. There may soon be a need to evaluate the ethical merits and concerns raised by proposals to implement “uncontrolled” DCD as well, but that was not a focus of this Subcommittee.

Subcommittee Membership

The Subcommittee included members from a range of departments and disciplines within the hospital. Approximately one-half of the membership was drawn from sitting members of the Bioethics Committee. Deputy county counsel and our bioethics lay community representative provided invaluable perspectives from outside of the Health Services Department.

Only one member of the Subcommittee had any familiarity with DCD procedures prior to the case that stimulated formation of this group. No members of the group had any ethical or religious objections to donation after brain death, or to transplantation generally. No members had direct professional or financial affiliation with any transplantation services. Several Subcommittee members described a personal connection with transplantation – meaning that the member him/herself, a family member, or a close friend had been an organ recipient in the past, or would likely need a transplant in the foreseeable future.

Subcommittee Process

During the past year, DCD Subcommittee activities have roughly followed a two-phased process: a “discovery” phase, followed by a “deliberation” phase. The discovery phase extended over the first eight months of the project and included the following:

- Reading of several hundred pages of background materials, ranging from ethical treatises and historical documents to technical procedure manuals and case studies, and from state statutes and governmental reports to short stories and newspaper articles.

- Interviews and/or meetings with individuals representing key regional programs, including:
  
  - California Transplant Donor Network (CTDN) – Several members of our
The deliberation phase extended over the last four months of the Subcommittee’s work. During this phase, members presented their individual views, explored options, and sought consensus. All told, the discovery and deliberation processes entailed approximately 20 hours of group discussion.
Discovery

The History of DCD

How do we know when someone is dead? What are the medical criteria for death? Outside of fears of being buried alive (nurtured by literary imagination), these questions were of only theoretical interest … until new medical technologies spawned important practical consequences to the answers we divined. Thus, our abilities to resuscitate and maintain a patient on life-support meant that a person who appeared dead, a person who had stopped moving and breathing and whose heart had stopped beating, still might not actually be dead. This new reality demanded a more formal clinical definition of death as “irreversible cessation of circulatory and respiratory function” – known as the “cardio-respiratory definition.”
The emergence of transplantation technology spurred further debate around the criteria for determining death. The first successful major organ transplantation (in 1954) involved a live, identical twin donor. Subsequently, with the development of immunosuppressant drugs in the 1960s, organs could be successfully transplanted from less ideally matched donors. This expanded the pool of potential transplantable organs to include unrelated cadaver donors. And, indeed, in these early years of transplantation, cadaver donors – persons who had been declared dead according to the cardio-respiratory definition (“non-heart-beating donors” or NHBD) – constituted the primary source for organs. Of course, there were major problems with the organs retrieved from this donor pool. Successful transplantation requires fresh, viable organs. The inability to precisely predict when a patient might suffer cardiac arrest, protracted resuscitation efforts, and the time necessary to pull together a surgical team to recover organs, all dictated against a reliable supply of viable organs from cadaver donors.

Coincident with these early transplantation efforts, a new category of patients was recognized. These were patients who had suffered severe, irreversible injury to the whole brain – and yet their cardiopulmonary and organ function could be maintained, for a limited period of time, by technology. When these patients finally sustained cardiopulmonary arrest, as they invariably did despite continuation of life-support systems, autopsies showed widespread necrosis of brain tissue. To many, these patients with irreversible destruction of the whole brain could and should reasonably be considered dead even before cessation of circulatory and respiratory function. And, if these were indeed cadavers, they would represent an ideal source of fully perfused, viable organs for transplantation.

In 1968, a Harvard Medical School committee recommended criteria for reliably diagnosing this class of patients who had sustained irreversible loss of function of the entire brain, including the brainstem. Subsequent study confirmed that no patient diagnosed by these criteria ever recovered. The argument was made that these patients – despite ongoing function of organs other than the brain – were, quite simply, dead. For a number of years, there was widespread debate in both public and professional settings, but a consensus gradually emerged in support of this Harvard diagnosis of death – a.k.a. “brain death” or “whole brain death”. This was codified in state laws and in the Uniform Determination of Death Act (UDDA) as drafted by the National Conference of Commissioners on Uniform State Laws in 1980 and endorsed by the American Medical Association, the American Academy of Neurology, and the American Bar Association. The UDDA succinctly states:

An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

The acceptance of this dual definition of death established a new class of prospective organ donors for transplantation. This group of brain dead, “heart-beating donors” (HBD) provided a valuable source of fresh, transplantable organs – much better than the poorly perfused organs obtained from non-heart-beating donors who had been declared dead by cardiopulmonary criteria. And so,
donation after brain death (DBD) quickly replaced donation after cardiac death (DCD) as the primary procedure for procuring solid organs for transplantation – and remains so today.

Improvements in science and technology led to a steady rise in the numbers of persons who could benefit from transplantation. Unfortunately, the supply of organs available from brain dead donors could not keep pace with this growing list of potential recipients. At the same time, an ethical and legal consensus had formed within this country in support of a patient’s (or his/her surrogate’s) right – acting in a process of shared decision-making with the physician – to refuse medical treatments, including life-sustaining technologies.

In 1992, the University of Pittsburgh Medical Center published a protocol for “controlled” donation after cardiac death. This “Pittsburgh protocol” detailed a process for organ procurement from patients who were on life-support but not brain dead. For this group of patients, if a decision to withdraw life-support was made and a desire to donate organs was expressed, the patient could be taken to the operating room with a transplantation surgical team standing at the ready. Under this “controlled” setting, life-support systems (ventilator, etc) would be withdrawn with cardiopulmonary arrest anticipated shortly thereafter. From the time of cessation of circulatory and respiratory function, a “stand-off period” would be observed (from 2-5 minutes) at the end of which the patient would be pronounced dead by cardio-respiratory criteria. The surgical team would then immediately enter for removal of organs for transplantation. This controlled approach minimized the critical period of organ ischemia from onset of hypotension or hypoxemia until organ recovery (“warm ischemia”) that had so plagued uncontrolled procedures for organ procurement from non-heart-beating donors. In so doing, the Pittsburgh protocol for controlled DCD offered an opportunity to harvest solid organs (not including the heart) from a group of donors who might otherwise go on to persistent vegetative state or sustain cardiac arrest in an uncontrolled circumstance.

The Pittsburgh protocol was immediately controversial within academia. A special issue of the Kennedy Institute of Ethics Journal (Volume 3; Number 2) was published in June 1993 under the title “Ethical, Psychosocial, and Public Policy Implications of Procuring Organs from Non-Heart-Beating Cadavers”. This publication included fourteen articles authored by eminent scholars from the fields of medicine, ethics, philosophy, religion, sociology, and the law. Questions of pressing public need, respect for the wishes of patients and families, manipulation of the definition of death for utilitarian purposes, conflicts of interest, and other important concerns were debated on either side of the controversy.

Despite the controversy, a few academic centers undertook procurement of organs by the Pittsburgh or similar DCD protocols. Then, in 1997, 60 Minutes aired a television program entitled “Not Quite Dead” in which it was suggested that, in some centers, organs were being removed from neurologically impaired and dying, but not yet dead, patients. The Ohio Board of Pharmacy accused one physician from the Cleveland Clinic of “conspiracy to commit homicide so as to obtain organs” and the public prosecutor threatened to indict any doctor who procured organs under the DCD protocol.
In the wake of the resulting public furor, the U.S. Department of Health and Human Services instructed the Institute of Medicine to prepare a report on cadaveric organ donation. The IOM report, released in late 1997, sited the following foundational principles as standards for all cadaveric donors, including NHBDs (DCDs):

1. The societal value of enhancing organ donation.
2. Organ donors must be dead at organ removal. [the “dead donor rule”]
3. Absolute prohibition of active euthanasia.
4. Complete openness about policies and protocols.
5. Commitment to informed consent.
6. Respect for donor and family wishes.

The report’s general conclusion was that “the recovery of organs from NHBDs [i.e. DCD] is an important, medically effective, and ethically acceptable approach to reducing the gap … between the demand for and the available supply of organs for transplantation.” The IOM found that the ethical concerns raised by DCD were neither unique nor insurmountable.

The problems raised require attention, but they are, in fact, not significantly different from those that arise in cadaveric transplantation generally. The design and implementation of standards and procedural guidelines for organ recovery from NHBDs based on the principles that support the retrieval of organs from brain-dead donors, would address these problems and allow the development of non-heart-beating organ donation as an important source of organs for transplantation. Such an enhancement of organ donation would be of significant societal value.

Further, the IOM expressed concern that discrepancies or outright contradictions between local DCD policies and protocols would threaten public confidence in the procedure. To reduce such inconsistencies and promote national uniformity, the report included a list of recommendations for national policy:

1. Procurement only with written, locally approved NHBD protocols.
2. Public openness of NHBD protocols.
3. Case by case decisions on anticoagulants and vasodilators. [See “procedure” discussion below.]
4. Family consent for pre-mortem cannulation. [See “procedure” discussion below.]
5. Conflict of interest safeguards – separate times and personnel for important decisions.
6. Determination of death by cessation of cardiopulmonary function for at least 5 minutes [“stand-off time”] by EKG and arterial pressure monitoring.
7. Family options (e.g. attendance at life support withdrawal) and financial protection.

The IOM study generated significant controversy with respect to its ethical reasoning and recommendations. For supporters of DCD, however, this report became (and remains today) the ethical “go-ahead” for efforts to develop and implement protocols throughout the country. Since publication of the IOM findings, Organ Procurement Organizations have urged hospitals to develop DCD policies and have offered template protocols for consideration. The DHHS Advisory Committee on Organ Transplantation, the AMA’s Council on Ethical and Judicial Affairs, and the Ethics Committee of the American College of Critical Care Medicine have all issued
recommendations supporting DCD procedures. A 2004 JCAHO white paper concluded that, “Bearing in mind the strong consensus in the expert community, hospitals should work with their affiliated OPOs to develop and implement policies that will facilitate expansion of organ recovery from DCDs.” And, in 2005, a national conference on DCD was convened “to expand the practice of DCD … and to affirm the ethical propriety of transplanting organs from such donors.” This group came to conclusions and made recommendations on a wide range of issues regarding DCD. Among these, it made “specific recommendations to agencies and organizations to remove barriers to DCD”, including a call for JCAHO to “revise accreditation standards to require hospitals to implement DCD protocols.”

The DCD Procedure

Current DCD protocols vary significantly in terms of important procedural specifics. Nonetheless, there is a foundational structure common to all. The following elements describe a rough chronological flow through the process of controlled DCD – and each raises specific ethical issues.

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1. Identification of candidates: Clinicians must first identify whether a patient is a potential DCD donor. There is agreement that, to be considered for DCD, the source patient must be expected to yield viable organs and must be likely to sustain cardio-respiratory death within a relatively short time (maximum 2 hours) following withdrawal of life support. Most protocols identify patients with severe, irreversible brain injury who do not meet brain death criteria as the primary candidates for DCD. Some include patients with debilitating illnesses such as ALS, high spinal cord injury, or advanced musculoskeletal disease. A criterion of “imminent death” may or may not be required.

2. Consent for withdrawal of life-support: The decision to withdraw life-support follows the same ethical standards for end-of-life decision-making that apply in cases not involving potential DCD. All DCD protocols envision a separation of the decision to withdraw
support from the consent process for DCD. This means that the clinical staff should not raise the question of DCD before a decision to withdraw support has been made; nor should OPO staff have contact with the family before such a decision has been made.

3. **Consent for DCD:** After a decision to withdraw life-support has been made, consent for DCD is obtained. The primary physician may initiate discussion of DCD donation with the family; alternatively, the OPO representative may raise the question. In either case, the OPO provides detailed information and secures the informed consent. For patients who are incapacitated, essentially all protocols require either the prior consent of the patient (as evidenced by a formal advance directive, driver’s license, or listing on the donor registry) or the informed consent of the family. Some may make an exception to this rule and allow procurement without consent from an incapacitated patient for whom no appropriate surrogate can be found (an “unbefriended” patient). For conscious patients with intact decision-making capacity, informed consent is required from the patient.

4. **Pre-mortem interventions:** In the interest of assessing and maximizing organ quality, the donor patient necessarily undergoes invasive procedures before the declaration of death. These procedures would *not* be undertaken in a non-donor patient in the same condition. Every donor patient must have basic screening studies (blood tests and the like). Other more invasive and risky pre-mortem interventions included in protocols for the explicit purpose of organ salvage may include bronchoscopy (to assess utility of lungs for transplantation), high dose intravenous heparin (to limit clotting within organ vessels), intravenous phenolamine (for vasodilatation), arterial line placement (for monitoring), insertion of perfusion cannulas (for rapid cold-flushing of organs post-mortem), and CPR with advanced life support measures (in the event that the patient arrests before everything is prepared for a controlled death).

5. **Withdrawal of life-support:** Under most protocols, the patient is transferred to the operating room where withdrawal of life-support is effected by the primary physician. (Involvement of an anesthetist is not required.) Family is given the option of attending the withdrawal and dying process. Other procedures call for an option to withdraw in the ICU or more comfortable setting, with rapid transport to the OR immediately following declaration of death. Standard palliative care measures for the end-of-life setting are continued or initiated as appropriate.

6. **Stand-off and declaration of death:** Following withdrawal of life-support, the patient is monitored closely. The required method of monitoring varies among protocols (from arterial line pressures and continuous EKG to clinical palpation and auscultation). The time at which there is full cessation (variably defined) of cardiac and respiratory function is noted. After a “stand-off” period of continuously absent cardio-respiratory function, the patient is declared dead. Protocols can vary in terms of the required stand-off time: most specify 5 minutes; others 2 minutes; rarely 1 or 10 minutes; occasionally no time is specified or is left to the judgment of the physician.
7. **Organ removal:** Following the declaration of death, the family leaves the room (or the patient is taken to the OR if withdrawal occurred in the ICU), and the surgical team immediately enters to remove the organs.

8. **Return to ward:** If the patient does not die within a specified length of time following withdrawal from life-support (1-2 hours), the patient is returned to the ICU or ward for ongoing care, and the family so informed.

9. **Financial coverage:** Most protocols specify that neither the family nor the hospital should bear the costs of the DCD process.

**Ethical Arguments in Support of DCD**

The Subcommittee identified the following arguments favoring implementation of a DCD protocol:

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**DCD saves lives:** The gap between the number of individuals needing transplantation and the number of organs available continues to grow. There are 90,000 persons on transplantation waiting lists in the US and roughly 6,000 patients die each year while waiting for an organ.

Growth in # transplants and # waiting list candidates over time.
(Source: HRSA and SRTR 2006)
We need to explore all available options for increasing the pool of donors. Through the 1990s, DCD accounted for roughly 1% of donations. Estimates vary, but supporters envision the potential for a fully implemented national DCD program providing up to 25% of donor organs. There can be a pejorative connotation to “utilitarian” ethical arguments, but the recipients of these organs are real, individual, suffering persons who can be returned to their families and productive lives by the “gift of life”.

**DCD honors the wishes of patients and families:** Many patients and families want to be organ donors. They should not be denied this opportunity. Once a decision has been made to withdraw life-support, organ donation should be an option for end-of-life planning. There is an ethical, legal, and social consensus that patients or their surrogates have a right to withdraw life-support. At the same time, patients and families have a right to be organ donors. Therefore, they should have the right to elect withdrawal of support followed by donation. The emphasis on patient autonomy in medical ethics over the past 50 years has been based upon a recognition that the health care professional has a responsibility to work toward the patient’s good as defined by the patient – not by the physician or profession. For many patients, the “good” they envision at the end-of-life extends beyond physiology to include an option for the gift of donation.

Critics of DCD are right to point to a potential for conflict-of-interest between the goal of obtaining organs for transplantation and the responsibility to serve the patient. This is why it is agreed that DCD should not occur outside of the procedural protections offered by carefully written protocols. Such safeguards include: adherence to existing standards for informed consent; assurance that the decision to withdraw life-sustaining treatment is made prior to initiating discussion of donation; and a strict functional separation between staff who are responsible for the care of the donor patient and procurement personnel prior to the decision to withdraw support and in the actual process of withdrawal and determination of death.

**DCD eases family suffering:** DCD can provide comfort and support to donor families. Many families report finding some “meaning” in the midst of senseless loss and tragedy through the act of donation. As the patient’s life comes to a close, health care professionals should be particularly attentive to the welfare of the family. DCD is one way to respond to their suffering.

**DCD nurtures community:** Beyond the lives of individuals directly affected by the organ donation process, the community at large stands to benefit from DCD. Such efforts foster altruism and have the potential to contribute to scientific and technological progress in ways we may not even anticipate.

**DCD has achieved consensus support:** The moral consensus supporting current transplantation practice requires that the care of the patient not be compromised in any significant way by virtue of a decision to donate organs. Furthermore, the “dead donor rule” dictates that vital organs must only be taken from dead patients (and that living patients must not be killed by organ retrieval). DCD is consistent with these standards.
DCD has been studied from an ethical perspective by a number of expert panels and health care leadership organizations, including the Institute of Medicine, the Society for Critical Care Medicine, and the World Health Organization. Each of these groups has judged DCD ethically acceptable and has recommended implementation of protocols. The US Department of Health and Human Services Advisory Committee on Organ Transplantation has issued recommendations supporting a move toward DCD. A broad spectrum of the medical community gathered in April 2005 for a National Conference on Donation after Cardiac Death. This interdisciplinary group affirmed the ethical propriety of DCD, detailed consensus positions on procedural elements, and proposed an action plan for increasing DCD practices. In 2004, an expert roundtable of the Joint Commission on Accreditation of Healthcare Organizations issued a public policy action plan to address the organ donation gap. This action plan included instruction that “hospitals should work with their affiliated OPOs to develop and implement policies that will facilitate expansion of organ recovery from DCDs.” It is likely that JCAHO will include an expectation for DCD implementation in its 2007 Hospital Leadership Standards. There is, indeed, a consensus on the ethical propriety of DCD, as well as a nationwide call to implement DCD protocols.

Ethical Arguments in Opposition to DCD

The Subcommittee identified the following arguments opposing implementation of a DCD protocol:

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<tr>
<td>Conflicts-of-interest and decreases trust</td>
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<td>Counters progress in end-of-life care</td>
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<tr>
<td>Ignores social justice issues (uninsured)</td>
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<tr>
<td>Lacks social consensus (bad process)</td>
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<tr>
<td>May decrease donations</td>
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<tr>
<td>Feels intuitively wrong</td>
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**DCD poses unacceptable conflicts-of-interest:** The primary, unambiguous responsibility of the health care professional is to serve the good of the individual patient. Indeed, etymologically, “profession” means “to make public declaration”, and the core declaration made by health care professionals is to serve the patient – not one’s own interests; not the interests of the hospital, the health plan, or society; not even the interests of the family if such service comes at the risk of compromising care for the patient. In some circumstances, it is impossible to disentangle inescapable conflicts of responsibilities (“de facto” conflicts-of-interest) from the practice of medicine. For example, continuity of care is a definite good for the patient, but a physician cannot be expected to neglect all personal and family responsibilities to be available to the patient 24 hours a day, seven days a week. For such instances of unavoidable conflicting responsibilities, procedural safeguards and the ethical identity of the professional must be relied upon to reasonably
minimize the potential for harm to the patient. However, before adopting an optional, new structure of professional accountability to interests other than those of the patient, the onus is upon medical professionals to assure not only that potential for risks to the patient have been minimized, but also that such risks are, in fact, negligible.

DCD protocols address the admitted potential for conflicts-of-interest influencing decisions to withdraw life-support and declarations of death by uniformly requiring a decoupling of decisions and personnel. Thus, the decision to withdraw support must precede discussion of donation, and procurement personnel must not participate in the actual withdrawal procedure and subsequent determination of death. Such structural protections, while certainly necessary if DCD is to be undertaken, rely upon an overly simplistic view of a complex reality. Even in the absence of the potential for organ donation, decisions to withdraw life-support are a complex stew of ethical, psychological, cultural, and social factors. Our ethical, legal, and social consensus favoring a patient’s or surrogate’s right to withdraw care is not an unrestricted license to decide. Surrogates are not always without self-serving motives and psychological antipathies that can push their decisions outside the realms of substituted judgment or even best interests of the patient. Provider dispositions, biases, and prejudices can color the presentation of prognoses and recommendations to families. For some families, particularly the poor and those historically exploited, the recent emphasis upon bedside cost-containment in medicine has raised suspicions that their loved ones may be sacrificed for the benefit of society. DCD protocols seek to add accountability to the interests of those on transplantation waiting lists to this ethically complex terrain. And while it may seem “impolite” to examine the motives of those in the transplantation community who are engaged in “saving lives”, it is a reality that transplantation services’ economic growth and prestige depend upon increasing the supply of organs. Pointing out such conflicting interests does not logically require a rejection of DCD on ethical grounds. It does, however, suggest that it is naïve to believe that the proposed procedures will protect against inappropriate influence in end-of-life decision-making in the face of a widespread implementation of DCD practices. Brain death is something that “happens” to the patient; DCD, on the other hand, is the product of a negotiation – subject to a range of unconscious motivations. As stated by one critic in the 1993 Kennedy Institute of Ethics Journal:

[We cannot characterize the process of DCD as a] series of isolated links, each to be understood solely as directed to the patient’s needs of the moment, each entirely disconnected from all surrounding context, including the very purpose of the exercise… However meticulously scripted the step-by-step [protocol], … and however unrelenting the drumbeat of insistences, … [it] is impossible to take these assurances at face value in the context of a transaction whose entire purpose and reason for being is to bring about the death of the patient in a fashion that produces viable organs.

The moral license for medical professionals to enter the lives and bodies of patients rests upon a promise to jealously guard the welfare of this single, suffering and vulnerable human being against competing interests. In this sense, medicine is emphatically non-utilitarian. DCD poses an unacceptable challenge to this moral foundation.

DCD manipulates the definition of death to avoid breaking the “dead donor rule”: In a number of
ways, the DCD procedure should give us pause as to whether we are, in fact, taking organs from patients who have not yet died. DCD relies upon the “irreversible cessation of circulatory and respiratory functions” criterion from the Uniform Determination of Death Act. But is the cessation of cardiopulmonary function in DCD cases really “irreversible”? Supporters of DCD argue that if enough time elapses to preclude auto-resuscitation and there is no desire or intent to resuscitate, then the irreversibility criterion is satisfied and the patient is dead. Consider a high cervical cord patient who has elected to withdraw ventilatory support. The patient is taken to the OR where the ventilator is disconnected. Within a short time, the patient sustains cardiac arrest. Two (or five) minutes later the patient is declared dead and organs are removed. Was this patient really dead at the time of organ excision? Certainly, resuscitation (cardiovascular and cerebral) was possible after two (or five) minutes of anoxia even if auto-resuscitation is no longer possible. It is an odd definition of death that depends upon the intentions of those in the operating room.

Don’t we frequently pronounce the death of patients in the ICU immediately after cardiac arrest, without waiting even two minutes? DCD simply follows this current practice – so it is argued. But the process of DCD changes the moral landscape of pronouncing death. For the typical patient dying in the ICU, there is no practical or moral difference between “certainly and imminently dying” and “dead”. There is no plan to surgically remove vital organs at the moment of death – as there is with DCD.

In the public debate over instituting the neurological criteria for death, a major argument was that cardiac death has always really been a surrogate criterion for brain death. And yet, DCD protocols do not involve assessment of, and make no claims about, cessation of all brain function at the time of organ removal.

The incoherence of the DCD concept of death is further evident in the diversity of protocols. Can it really be “true” that a patient is dead at a point five minutes after cardiac arrest on one side of the Bay and at two minutes on the other side? These issues and inconsistencies are the source of concerns that DCD manipulates subtle ambiguities in the definition of death to allow organ procurement from a new source, while claiming adherence to the dead donor rule.

**DCD violates the promise to “do no harm”**: Aside from the question of whether DCD removes organs from patients who are dying but not certainly dead, the pre-mortem interventions often included in the process (e.g. bronchoscopy, heparin, phentolamine, cannula insertion) constitute transgressions of the principle of non-maleficence. These procedures pose variable, but definite, risk for the patient and cannot be ethically justified by the benefit accruing to others. It is also not uncommon for the patient to defy predictions of rapid arrest following withdrawal of life-support. The patient is then returned to the ICU or ward – in worse condition than when taken to the OR. The patient’s deterioration, and the family’s heightened suffering, certainly constitutes very real harm caused by the DCD procedure.

**DCD “plays loose” with standards of informed consent**: The moral validity of a surrogate’s preferences for the treatment of a patient is not a given. We require that the surrogate first act in concert with what the patient him/herself would choose – were he/she able. Absent sufficient
information to make such a “substituted judgment”, the proxy is expected to act in the patient’s best interests. It is hard to imagine how a surrogate can know what a patient would decide with respect to DCD when very few individuals (including very few physicians) have any notion as to what is involved in the process – or of the ethical controversies surrounding this procedure. Are the surrogates informed of the ethical issues raised by DCD during the consent process? We might especially expect that the “dying” vs “dead” debate should be explored with families since surveys show that one of the major reasons given for not registering to be a donor is a fear that organs will be taken before actually dead.

When it is impossible to know what an incapacitated patient might have decided for a proposed medical procedure, the accepted standard is for the surrogate to act in the patient’s best interest. We generally protect vulnerable patients from surrogate decisions that accept more than minimal risk for the patient in the service of social interests, no matter how noble (e.g. consent for human research involving minors). The alert patient with intact capacity (e.g. a patient with ALS, MS, or cervical cord injury) is most likely to meet the criteria for a truly informed consent. But this class of patients is frequently omitted from DCD protocols.

**DCD creates a “slippery slope”:** The gap between needy recipients and available organs will not be solved by DCD in any current scenario. Pressures will continue to push the edges of candidacy for DCD. There are somewhere between 15,000 and 35,000 Americans with the diagnosis of persistent vegetative state. A survey of neurologists and medical directors in 1993 showed that almost two-thirds of responders believed that “it would be ethical to use the vital organs of patients in the PVS for transplantation” after a decision had been made to discontinue all therapy so that death became inevitable. Will these PVS patients become a major source for organs? Or, can we expect Oregon (and perhaps soon other states that legalize physician assisted suicide) to implement a process of “controlled suicidal donation” in which the terminal patient is admitted to the OR where he/she voluntarily imbibes a fast-acting suicidal agent, and organs are removed 2-5 minutes after cardiac arrest?

Our practices tend to shape morality – we get used to things and they lose their ethical sting. When DCD becomes accepted, “meaningful”, and laudatory, will we overlook the inherent uncertainty of prognosis in the first days following a major head injury and, inadvertently, declare futility too quickly? This notion of finding “meaning” for tragedy and suffering through the altruistic act of DCD is morally complex. There may be a subtle and unintended, but potentially coercive, message sent to those with severe illness and disabilities: “Your life will have meaning if you end it so that others may live.”

**DCD counter progress in end-of-life care:** Some champions of the hospice and palliative care movements are troubled by the prospect of DCD. They fear that recent progress in the areas of communication, relationship work, relief of suffering, and spiritual care will be effaced by a scripted, high-tech death. Renee C. Fox, a professor of social sciences, writing for that 1993 Kennedy Institute of Ethics Journal, expresses this view:

If asked to identify what is most dreadful about it [DCD], I would single out the desolate,
profanely “high tech” death that the patient/donor dies, beneath operating room lights, amidst masked, gowned, and gloved strangers, who have prepared his (her) body for the eviscerating surgery that will follow… This contrasts sharply with the procedures that the nursing and medical staff responsible for the care of hospitalized, non-donor patients try to follow when they sense that an imminent death is approaching… What the protocol asks of donors, their families, and caretakers goes so far beyond the pale of the medically decent, morally allowable, and spiritually acceptable that it strains credulity…

The delicate consensus that has been reached around withdrawal of care and palliation at the end of life may unravel if the public recognizes in DCD just the sort of slide down the slippery slope that many feared.

**DCD ignores social justice issues in allocation:** Years ago, federal legislation provided funds to eliminate “ability to pay” as a criterion to qualify for kidney transplantation. Such funding does not exist for transplantation of other organs. Transplant centers often require uninsured or underinsured patients to place large down payments before they will be placed on the waiting list. Advocates for these patients can reasonably question the morality of a campaign to increase procurement of organs without first – or at least concurrently – addressing the inequity of a system that allocates organs based, in part, on ability to pay. Fair distribution of benefits and burdens, with special attention to the status of disadvantaged groups, should be a foundational principle of any plan for addressing the organ gap in this country.

**DCD lacks a social consensus:** The campaign to define, approve, and implement DCD primarily reflects the agenda and efforts of the transplantation community. This is not a bad thing. We need and expect experts in the field and those most personally affected by transplantation to provide visionary leadership. On the other hand, it is neither unfair nor discourteous to suggest that those closest to the process – those whose life work, livelihood, and very lives depend upon our ability to procure and transplant organs – may have a particular slant on the ethical issues raised by DCD.

Since the IOM report in 1997, the discussion of DCD has been largely an exercise in “how to”, rather than “whether”. From its inception, the IOM’s commission from the DHHS contained a presumption of its conclusions:

> Given a potential donor in an end-of-life situation, what are the alternative medical approaches that can be used to maximize the availability of organs from that donor without violating prevailing ethical norms …? The Institute will consider the alternative approaches, including the use of anti-coagulants or vasodilators …

This charge seemed to leave little room for the possibility that “prevailing ethical norms” may not be adequate to address the moral dimensions of a new approach to procurement. And the openly acknowledged “starting point” for the IOM study offered little hope for those who were anticipating an unbiased exploration of *whether or not* DCD was a good idea:

> The premises that organ transplantation is a valuable treatment that should be supported and extended to all suitable patients with organ failure and that organs from NHBDs are an underutilized, although potentially very significant, source of organs for transplantation
that deserves careful exploration were starting points for this report. [Italics added.]

The report reflected “a new kind of effort for the IOM” in that it utilized a single principal investigator, with advice from a panel of eight Senior Special Experts. These experts came from various academic positions within the fields of medicine, ethics, and the law. The group conducted a day-long workshop on NHBD transplantation, entitled “The Medical and Ethical Issues in Maintaining the Viability of Organs for Transplantation”. According to the principal investigator, the workshop participants provided a “foundation for the analysis, findings, and recommendations of this report.” So, who were the contributors to this foundation? Here’s the complete list of presenters:

- Director, Division of Transplantation, HRSA
- President, United Network for Organ Sharing
- Executive Director, California Transplant Donor Network
- Executive Director, New Mexico Donor Program
- President, American Society of Transplant Physicians
- UCLA Professor of Medicine and Surgery (and developer of model to increase donors from all sources, including NHBDs)
- Past President, North American Transplant Coordinators Organization
- Executive Director, Delaware Valley Transplant Program
- Chair, National Donor Family Council
- Past President, American Association of Kidney Patients
- Executive Director, Transplant Recipients International Organization
- Heart Recipient
- University of Wisconsin, Transplant Surgeon (where NHBD procurement had been performed continuously since 1974)
- University of Pittsburgh, Professor of Medicine (where the “Pittsburgh Protocol” for DCD was developed)
- University of Virginia, Professor of Religious Studies

Again, the contributions of these leaders are critical to any discussion of transplantation policy. But if the intent were to consider not just how to implement DCD, but whether DCD was a good idea, the list of invitees might have extended beyond representatives of the transplantation community. We can only wonder what the recommendations of the IOM might have looked like if discussion had included members of minority groups who may not hold the medical profession in such high regard, or advocates from the disabled community, or any of the ethicists and scholars who had written eloquently about their concerns with DCD.

With the go-ahead from the IOM, DCD has gained momentum. A number of professional organizations have endorsed the procedure. Organ procurement organizations have assertively pushed the DCD agenda, providing templates for hospital protocols and policies. There is a palpable presumption that the matter has been settled – ethical qualms have been addressed – a consensus has been reached. The Joint Commission convened an “expert Roundtable” which recommended implementation of DCD protocols. Their report, Health Care at the Crossroads:
Strategies for Narrowing the Organ Donation Gap and Protecting Patients, concludes its brief discussion of DCD with the following:

Bearing in mind the strong consensus in the expert community, hospitals should work with their affiliated OPOs to develop and implement policies that will facilitate expansion of organ recovery from DCDs.

In April of 2005, a national conference on DCD was convened “to expand the practice of DCD” and “to affirm the ethical propriety of transplanting organs from such donors.” The conclusion of their report reads:

The National Conference on DCD affirmed DCD as an ethically acceptable practice of end-of-life care, capable of increasing the number of deceased-donor organs available for successful transplantation. [Italics added.]

The term “affirmed” is well chosen since the body of the report contains pronouncements of what should be done, but essentially no discussion of the substantive ethical concerns that have been raised by critics of DCD.

The concern here is that – from the Pittsburgh protocol to the IOM report to the JCAHO Roundtable to the National Conference – DCD primarily reflects the agenda and priorities of the transplantation community. There has been very little input from either the general medical community or the public at large. In fact, very few persons – professional or lay – know what DCD stands for or have any sense of how it differs from DBD. A consensus of “the experts” is ethically insufficient to justify a procedure that touches on such profound issues as the definition of death, the nature of the physician-patient relationship, and the allocation of health care resources. A national strategy for addressing the pressing need for organs must be the product of a wider discourse, if it is to claim consensus.

DCD may actually result in a decrease in donation: Every group to study DCD has been alert to the importance of public opinion. Even its most ardent supporters recognize that a negative public reaction to DCD could jeopardize current levels of donation, with the potential to actually decrease the supply of organs. This is not just a theoretical concern. Past experience has taught us that donor supply is, indeed, susceptible to public distrust.

We might imagine two distinct strategies to address this important concern. One approach would be to nurture a broad, open civil discourse around the issues raised by DCD (and organ supply generally). The other approach – which seems to be the current path – is to move for approval and implementation of DCD procedures within medical centers and hospitals, while limiting public discussion to carefully crafted talking points. Thus, Work Group 6 (“The Media, Public Perceptions and DCD”) of the National Conference on DCD does not call for public forum discussions or for pro/con debates on television or radio. They do provide a bulleted list of “the public message to be conveyed about DCD”:

- DCD honors donor wishes in the continuum or quality end-of-life care.
• DCD can provide comfort and support to donor families.
• DCD saves lives.

In private, many DCD supporters will roll their eyes at the suggestion of wider civil discourse around a topic as technically complicated and ethically charged as DCD. Given the tone of public debate in our country, they expect little could be gained from such efforts. Even raising the topic might negatively impact current donor levels. While this cynicism may not be without some foundation, it underpins a paternalism that is unacceptable in our society. Furthermore, we should be very concerned about any proposal that is so morally sensitive as to preclude public airing.

*DCD feels intuitively improper:* For many, including some members of the hospital staff, there is an intuitive sense that the DCD process is improper – even profane. Again, in the words of Professor Renee Fox:

> [I]n my view, the kind of “rational mutilation of the body” and “death by protocol” that are involved here desecrate what is sacred about human bodily life and bodily death, and brings us close to the foreboding image once invoked by theologian Paul Ramsey: the reduction of persons to “an ensemble of … interchangeable … spare parts” in which “everyone [becomes] a useful precadaver.”

In ethical disputation, we – especially those of us working in the scientific paradigm – tend to value rational and utilitarian arguments to the exclusion of the intuitive and affective. This emphasis is not shared by all, or even most, in our society. The intuitive sense of “good and bad” and “right and wrong” does not require a religious persuasion, but insists that there is an important component to ethical judgment that is pre-rational.
Deliberations

Exploring a Permissive Policy

We concluded the “discovery phase” of our subcommittee’s work with an appreciation for the substantive ethical issues – “pro” and “con” – raised by DCD. It was apparent that support for DCD necessitates a carefully crafted structure of limits and protections. To explore the possibility of writing such a policy that could protect against the identified ethical concerns, we next engaged a thought experiment. We began this exercise with the false premise that we must write a policy permissive of DCD. This allowed us to consider the practical implications of some of the theoretical ethical issues and to see whether we could reach consensus around a policy. Thus, the entire committee membership, including those who had major reservations about DCD, agreed to accept the premise and work toward a permissive policy.

We began this exercise by considering three major, practical dimensions of any DCD policy:

1. Candidates: (Which groups of patients should be considered candidates for DCD? Which should not?) Three major categories of patients were distinguished:

   a. “Unbefriended” patients (i.e. patients with no decision-making capacity, no surrogate, and no DCD advance directive): There was unanimous agreement that this group should not be eligible for DCD.

   b. Patients with intact decision-making capacity (DMC): Here, the majority felt that a distinction should be made based upon whether “imminent death” applied – i.e. death is imminent even if life-support is continued. Thus, the majority of our group would lean toward inclusion of patients for whom death was imminent (e.g. patients with end-stage ALS), while the majority favored exclusion of patients not meeting the imminent death criterion (e.g. stable, ventilator-dependent patients with high cervical cord injury).

   c. Patients without DMC, but with a surrogate (e.g. s/p severe brain injury – anoxic or traumatic; this is the primary target group envisioned for DCD efforts): No consensus could be reached for this group of patients. All agreed that certainty of prognosis was important for this group. Thus, patients for whom there was medical uncertainty as to prognosis should not be considered for DCD. We did not resolve whether this meant certainty of imminent death or certainty of no “meaningful” future life. It was also suggested that prognosis should be determined only after a period (e.g. 24 hours) off of all CNS active medications. Again, no consensus could be reached for this group, but the majority was leaning toward inclusion if there was definite, irreversible neurologic devastation.
2. Stand-off time: (How much time should be required from cessation of circulatory and respiratory activity until declaration of death?) All agree that the stand-off time should be no less than 5 minutes. The group was evenly divided between a requirement for 10 minutes (with higher likelihood of brain death) and a mandated 5 minutes (with higher organ viability).

3. Pre-mortem interventions: (e.g. bronchoscopy, cannulation, heparin, phentolamine) The group was split between those who would allow no pre-mortem procedures that were not indicated for the health benefit of the patient, and those who would allow individual pre-mortem interventions if approved by the primary physician and accepted by the family after a fully informed consent. In the latter instance, it was emphasized that the consent should be a discussion between the primary physician and the family, without inclusion of the OPO representative.

Exploring a Non-Participation Policy

Having envisioned what a DCD-permissive policy might look like, the group next considered what a non-participation policy might involve, assuming that such a stance were required. Three critical dimensions of such a position were identified:

1. Transfer: (Should we cooperate with transfer of a patient to another facility where DCD is done, when so requested by the family?) There was unanimous agreement that any non-participation policy should include a willingness to cooperate with transfer if requested by the patient or family. No one felt that DCD represents a moral evil requiring a stance of non-complicity.

2. Disclosure: (Should every potentially eligible patient/family be informed of an option for DCD at another facility, whether they raise the issue or not?) The subcommittee was split over this question. Some members felt that respect for the autonomy of the patient/family requires a position of full disclosure. Others maintained that the very act of presenting this information – unsolicited – constitutes participation in the DCD process itself – a process that intrudes an unacceptable conflict-of-interest into the physician-patient relationship. These members further argued that DCD is not currently standard of care, and that there can be no obligation to offer a non-standard procedure. Even amongst active DCD-permissive policies in area centers, not all require offering this option to all patients/families. State law [California Health and Safety Code, Section 7184] requires that the family be informed of the option to donate organs and tissues “at or near the time of notification of death” with “reasonable discretion and sensitivity to the family circumstances in all discussions.” And hospitals with a Medicare provider agreement must ensure that the family of each potential donor is informed of its options to donate. It is unclear if these standards translate into a requirement to offer an option for DCD to the family of a patient for whom a decision has been made to withdraw life-support. The resolution of this question would seem to depend upon a social and/or legal consensus as to whether such patients should be considered
“potential donors”, or not. Despite this ambiguity, all members agreed that there must be no “gag clause” restricting open, honest communication between the primary physician and patient or family.

3. Moral traces: A moral dilemma typically involves a situation in which there are competing moral claims on both sides of an issue – such that making a decision for one side necessarily compromises important moral values on the other. “Moral traces” refers to the debt owed to the prima facie obligations that have been overridden by the chosen course of action. The subcommittee agreed that any non-participation DCD policy should be coupled with efforts to:

- Facilitate donor registry amongst staff and patients.
- Work with the OPO to maximize identification and appropriate management of candidates for organ donation after brain death and for other tissue donations.
- Cooperate with transfer for DCD, if specifically requested by family.
- Participate in respectful discussion and debate on the question of DCD and other efforts to narrow the organ gap, including advocacy for just allocation of resources irrespective of ability to pay.
- Remain open to change.
Conclusions

No single line of reasoning emerged from the subcommittee’s deliberations. Each member had a unique perspective on the various ethical dimensions of DCD. Subcommittee members were surveyed as to the relative weight of the various arguments. The opportunity to honor patient and family wishes for donation and the potential to save lives were clearly the most compelling arguments in support of DCD.

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<th>“Pro” Arguments</th>
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<th>“Most Compelling” (# votes)</th>
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<tr>
<td>Saves lives</td>
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<td>4</td>
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<tr>
<td>Honors patient &amp; family wishes</td>
<td>1.6</td>
<td>7</td>
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<tr>
<td>Eases family suffering</td>
<td>0.6</td>
<td>0</td>
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<tr>
<td>Nurtures community (altruism &amp; science)</td>
<td>0.5</td>
<td>0</td>
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<tr>
<td>Has consensus professional support</td>
<td>0.6</td>
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Survey of all subcommittee members’ opinions regarding “pro” arguments.
“Strength of Argument” score: 2 = very compelling; 1 = moderately compelling; 0 = not compelling.
“Most Compelling” = number of members identifying this argument as the strongest “pro” argument.

For arguments in opposition to DCD, there was a wider range of opinion. The most compelling “con” arguments involved concern that DCD poses conflicts-of-interest, compromises trust, and has been pushed by the transplantation community without achieving a social consensus.

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<td>Lacks social consensus (bad process)</td>
<td>1.6</td>
<td>3</td>
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<tr>
<td>May decrease donations</td>
<td>0.7</td>
<td>0</td>
</tr>
<tr>
<td>Is intuitively wrong</td>
<td>0.6</td>
<td>1</td>
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</table>

Survey of all subcommittee members’ opinions regarding “con” arguments.
“Strength of Argument” score: 2 = very compelling; 1 = moderately compelling; 0 = not compelling.
“Most Compelling” = number of members identifying this argument as the strongest “pro” argument.
Though we were unable to detail one unitary line of reasoning that is shared by all members of the subcommittee, a number of conclusions were possible. Our subcommittee found agreement on each of the following points.

- DCD presents a complex nexus of ethical issues – there’s nothing “simple” about this question. Characterizations of DCD proponents as organ-seeking ghouls and opponents as heartless theorists only detract from the important conversation that needs to take place.

- There are strong ethical arguments supporting implementation of DCD – most notably the potential to save lives and the opportunity to honor the wishes of the patient or family.

- The linear, deductive argument commonly presented in support of DCD, that being …

\[
\begin{align*}
\text{The right to withdraw life-support} & \\
+ \quad \text{The right to donate organs} & \\
= \quad \text{The right to DCD}
\end{align*}
\]

… is too simplistic. The practice of DCD substantively changes the moral landscape of end-of-life decision-making and raises new ethical issues that must be considered.

- The clinician’s primary responsibility must be to the individual patient. Utilitarian considerations of benefit to others are important, but must not trump this duty. Before accepting a structure that brings external interests into play at the bedside, we must be reasonably sure that such a structure will not compromise or unduly influence care of the vulnerable patient. A policy statement requiring separation of the decision to withdraw life-support from consent for donation, while necessary, may not be sufficient in this regard.

- The national process for DCD approval and implementation has been inadequate to date. A procedure with such far-reaching implications must emerge from a consensus that extends well beyond the transplantation and medical research communities – to include the wider medical community and the public at-large.

- Lack of broader community buy-in from the outset runs the very real risk of exacerbating public distrust of medicine, with resulting paradoxical reduction in donor rates. The ethically appropriate strategy to avoid this worst-of-all-possible scenarios is not to run a public relations campaign, but to promote truly informed and open civil discourse.

Committee members were not of a single mind on the complex issue of DCD. Where we could not find consensus, disagreements arose primarily from our individual assessments of:

- The degree to which ethical ambiguities and tensions should be tolerated in order to honor the preferences of donors and to secure the clear and substantial benefits for transplant recipients;
- The degree to which procedural safeguards written into a DCD policy can adequately protect against potential problems; and

- The degree to which weaknesses in the process for DCD approval and implementation to this point dictate a position of non-participation.

Nine members voted for non-participation with DCD, while two members felt that a carefully crafted policy and protocol for DCD should be adopted.

All members affirmed that the Subcommittee processes of discovery and deliberation were thorough and fair, and accepted the following consensus recommendations.
Recommendations

The Bioethics Subcommittee on Donation after Cardiac Death is fully aware of recent recommendations and pressures to implement DCD protocols throughout the US hospital system. Despite these efforts, on the basis of our ethical analysis, the Subcommittee submits the following recommendations to the CCRMC Medical Executive Committee and to Administration:

1. Do not implement DCD procedures at CCRMC.

2. Adopt the following policy with respect to DCD. (See page following.)

3. Present this report to Professional Affairs Committee or other appropriate oversight body.

4. Work with the OPO to maximize identification and appropriate management of candidates for organ donation after brain death (including Maastricht IV cases) and for other tissue donations. This shall include notifying the OPO of individuals whose death is imminent or who have died in the hospital.

5. Facilitate donor registry amongst staff and patients.

6. Participate in respectful public discussion and debate on the question of DCD and other efforts to narrow the organ gap. Such participation should include advocacy for just allocation of transplantation resources irrespective of the individual patient’s ability to pay. Our special position as “safety net” providers for the least advantaged members of our community obligates us to promote justice in allocation of health care resources – not as a topic for a future agenda, but as an integral element of any national strategy.

7. Identify a member of the professional staff to serve as CCRMC Organ and Tissue Donation Coordinator. The OTD Coordinator should coordinate organ and tissue donation activities at CCRMC, including: patient and staff education, donor registry efforts, execution of hospital policies, and communications with the OPO and other outside groups. The OTD Coordinator should present a summary of CCRMC donation activities to the Medical Staff President and Hospital Executive Director on an annual basis.

8. Remain open to change. DCD and other aspects of organ donation policies and procedures raise complex issues in a rapidly evolving social milieu.
CCRMC Policy on Organ Procurement through Donation after Cardiac Death (DCD)

After careful consideration, the Medical Staff has decided not to implement organ donation after cardiac death (DCD) procedures at CCRMC. This position is taken with full appreciation for the pressing need to increase our supply of organs available for transplantation in this country. Nonetheless, DCD presents a number of substantive ethical problems that dictate against its implementation. (For a full analysis of the ethical issues raised by this procedure, see the full report of the Bioethics Subcommittee on Donation after Cardiac Death, submitted to the Medical Executive Committee on October 16, 2006.)

The following policies and procedures shall apply to Donation after Cardiac Death at CCRMC:

1. Donation after Cardiac Death (DCD) procedures will not be done at CCRMC. (The only exception to this policy will be for Maastricht Category IV cases – see below.)

2. A decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ or tissue donation. If a patient or surrogate raises the issue of DCD, discussion should be deferred until after a decision to withdraw life-support has been made.

3. After a decision to withdraw life-support has been made, the physician may choose to discuss DCD with the patient/surrogate – or not. There is no duty to inform, nor is there a prohibition against such discussion.

4. In any discussion of DCD, staff should inform the patient/surrogate that DCD procedures are not done at CCRMC, and that this policy was approved by the Medical Executive Committee on the recommendation of the Bioethics Subcommittee on DCD. If additional information is desired, the clinician may refer directly to the Subcommittee’s report or seek consultation with the CCRMC Organ and Tissue Donation Coordinator, the Clinical Service Chief, the Bioethics Chair, the Medical Staff President, or the Administrative Officer of the Day.

5. At the request of the patient or surrogate, CCRMC will cooperate with transfer of the patient to another area center for purposes of pursuing a DCD procedure if:
   a. CTDN (the local Organ Procurement Organization) agrees to coordinate the transfer and gives assurances that transfer costs will be covered with no charge to either the patient/family or to CCRMC; and
   b. There is an accepting institution and physician.

6. In keeping with federal regulations, CTDN must be notified of all cases of patients whose death is imminent or who have died in the hospital. For cases in which the patient does not meet criteria for brain death, but death is imminent, CTDN should be reminded at the time of notification that CCRMC has a “No DCD” policy. CTDN should neither broach nor discuss DCD with a patient or family without the prior explicit request of either the patient’s attending physician or the CCRMC Organ and Tissue Donation Coordinator – and then only in the context of possible transfer to another facility.

This policy does not diminish or compromise CCRMC’s commitment to organ procurement following brain death - including the special case of a patient who has been declared dead by neurologic criteria (i.e. whole brain death) but subsequently sustains cardiac arrest. This situation has been classified as a subgroup of “uncontrolled” DCD (Maastricht Category IV), but is more accurately viewed as a special circumstance of donation after brain death.
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
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<tr>
<td>CCRMC</td>
<td>Contra Costa Regional Medical Center</td>
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<tr>
<td>DBD</td>
<td>Donation after Brain Death</td>
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<tr>
<td>DNDD</td>
<td>Donation after Neurologic Determination of Death</td>
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<tr>
<td>DCD</td>
<td>Donation after Cardiac Death</td>
</tr>
<tr>
<td>DCDD</td>
<td>Donation after Circulatory Determination of Death</td>
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<tr>
<td>DHHS</td>
<td>Department of Health and Human Services</td>
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<tr>
<td>CTDN</td>
<td>California Transplant Donor Network</td>
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<tr>
<td>HBD</td>
<td>Heart-Beating Donor</td>
</tr>
<tr>
<td>HRSA</td>
<td>Health Resources and Services Administration</td>
</tr>
<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
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<tr>
<td>KIEJ</td>
<td>Kennedy Institute of Ethics Journal</td>
</tr>
<tr>
<td>MEC</td>
<td>Medical Executive Committee</td>
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<tr>
<td>NHBD</td>
<td>Non-Heart-Beating Donor</td>
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<tr>
<td>OPO</td>
<td>Organ Procurement Organization</td>
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<tr>
<td>PVS</td>
<td>Persistent Vegetative State</td>
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<td>UDDA</td>
<td>Uniform Determination of Death Act</td>
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APPENDIX B

Glossary

**Autoresuscitation**  Spontaneous restoration of heart function after the heart has stopped beating.

**Brain death**  Death determined by neurologic criteria demonstrating irreversible cessation of all brain function, including the brain stem.

**California Organ and Tissue Donor Registry**  State registry containing information regarding persons who have identified themselves as organ and tissue donors upon death.

**Cannulation**  The process of placing silastic tubes (cannulae) into large blood vessels for the administration of fluids and/or medications, withdrawal of blood, or cold flushing of organs.

**Cardio-respiratory death**  Death determined by irreversible cessation of circulatory and respiratory function.

**Cold perfusion**  Cold solution is infused into large vessels and blood drained out to preserve organs before they are removed from the dead body.

**Dead donor rule**  Rule stating that the donor must be dead before organs are taken.

**Designated tissue bank**  Local tissue center with which a given hospital has a standing service relationship. Our designated bank is the UCSF tissue bank.

**Donation after brain death (DBD)**  Organ donation from a patient who is pronounced dead on the basis of irreversible cessation of all brain function, including the brain stem. Synonyms are “heart-beating donation” (HBD) and “donation after neurologic determination of death” (DNDD).

**Donation after cardiac death (DCD)**  Organ donation from a patient who is pronounced dead on the basis of irreversible cessation of circulatory and respiratory functions. Synonyms are “non-heart-beating donation” (NHBD) and “donation after circulatory determination of death” (DCDD). May be either “controlled” (cDCD) in which cardiac arrest is anticipated and the recovery team is present, or “uncontrolled” (uDCD) in which procurement can only be set in motion after an unanticipated moment of death.

**Heparin**  An anticoagulant medication that is used in organ procurement to keep vessels open and to maximize blood flow to the organs. Potentially, can cause bleeding complications.
**Ischemia** Lack of oxygen supplied to the tissues and organs. **Warm ischemia** refers to the period of time from the onset of hypoxemia until the organs have been cooled. Usually only 30-45 minutes can be tolerated by organs. **Cold ischemia** is the time from cold perfusion until the organ is transplanted into the recipient.

**Maastricht categories** A classification system for donation after cardiac death:

- Category I Dead on arrival at the hospital
- Category II Unsuccessful resuscitation
- Category III Awaiting death by cardio-respiratory criteria
- Category IV Cardiac arrest following brain death

Categories I, II, and IV are uncontrolled; category III is controlled. (Category IV may, more accurately be considered a special situation of donation after brain death.

**Organ procurement organization (OPO)** Federally designated non-profit organization locally responsible for facilitation of donor identification and care, organ removal and preservation, and transplantation of organs. Our local OPO is the **California Transplant Donor Network (CTDN)**.

**Phentolamine** A medication used in organ procurement to dilate blood vessels and increase blood flow to the organs and tissues. Potentially causes a drop in blood pressure.

**“Presumed consent” for donation** Policy proposal that would assume each person to be a donor unless he/she has opted-out. Presumed consent is in effect in some European nations. US policy currently requires an opt-in by the patient or surrogate.

**Stand-off period** Time from the loss of cardiac activity and blood pressure following discontinuation of life-support measures until declaration of death.

**Transplant coordinator** Employee of OPO responsible for working with donor families and hospitals. Coordinators are specially trained to respond to hospital referrals, educate staff, obtain consent, evaluate medical suitability of potential donors, medically improve organ function, and generally manage the donation process. The coordinator also accesses the transplant recipient waiting list maintained by UNOS to match donors and recipients.

**Uniform Anatomical Gift Act (UAGA)** Allows donation of body parts after death for various uses, including transplantation; first proposed in 1968; subsequently enacted in some form in all states [California Health and Safety Code, section 7150 et seq].

**United Network for Organ Sharing (UNOS)** Non-profit group under federal contract to control organ distribution in the US.
This document reports the findings and recommendations of the ad hoc Subcommittee only. This Subcommittee is strictly advisory. The content of this document does not represent the opinions or policy of Contra Costa Regional Medical Center, its Medical Staff, Administration, or governing Board.

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