

The Canadian Council for Donation and Transplantation

# **Donation After Cardiocirculatory Death:**

*A Canadian Forum*

February 17–20, 2005

Vancouver, British Columbia

**Report and Recommendations**

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July 2005

ISBN 0-9738718-0-6

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Production of this advice/report has been made possible through a financial contribution from Health Canada.

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## Electronic Versions and Background Documents

The following documents can be downloaded from the CCDT website at [www.ccdt.ca](http://www.ccdt.ca):

1. Steering Committee, Donation after Cardiocirculatory Death: A Canadian Forum (2005). *Donation after Cardiocirculatory Death: A Canadian Forum: Report and Recommendations*. Edmonton: The Canadian Council for Donation and Transplantation.
2. Baron, L. (2005). *Donation after Cardiocirculatory Determination of Death: A Review*. Edmonton: The Canadian Council for Donation and Transplantation.
3. Glannon, W. (2005). *A Review of Ethical Issues Surrounding Donation After Cardiocirculatory Determination of Death*. Edmonton: The Canadian Council for Donation and Transplantation.
4. Zaltzman, J. (2005). *Organ Donation After Cardiocirculatory Death: Allograft Outcomes*. Edmonton: The Canadian Council for Donation and Transplantation.
5. Steering Committee, Medical Management to Optimize Donor Organ Potential: A Canadian Forum (2004). *Medical Management to Optimize Donor Organ Potential: A Canadian Forum: Report and Recommendations*. Edmonton: The Canadian Council for Donation and Transplantation.
6. Planning Committee, Severe Brain Injury to Neurological Determination of Death: A Canadian Forum (2003). *Severe Brain Injury to Neurological Determination of Death: A Canadian Forum: Report and Recommendations*. Edmonton: The Canadian Council for Donation and Transplantation.

## Preface

There are two fundamental but not mutually exclusive perspectives on organ donation:

- As an important part of end-of-life care, patients who die should be provided the opportunity to donate organs and tissues.
- Potential transplant recipients, who would otherwise die or be substantially compromised, can benefit from initiatives that address the current shortage of organs for transplantation.

Current Canadian practice supports organ donation after death as determined by neurological criteria and tissue donation after death determined by cardiocirculatory criteria. However, contrary to international practice and historical practice in Canada prior to brain death criteria, organ donation after cardiocirculatory death has not been offered to dying patients in Canada and is not available to families who request it. Reflecting these perspectives, the Canadian transplant and donation communities have called for the establishment of this form of donation.

The Canadian Critical Care Society, representing Intensive Care Unit physicians caring for critically ill patients, strongly supports collaborative initiatives to develop, implement and evaluate processes to increase organ and tissue donation within a sound legal and ethical framework. At the same time, they have cautioned against proceeding with donation after cardiocirculatory death (DCD) without a comprehensive national discussion. In the province of Quebec, a recent consultative report by the Commission de L'éthique de la Science et de la Technologie has addressed a number of the ethical issues inherent to this form of donation.

The purpose of the Canadian Council for Donation and Transplantation (CCDT) is to strengthen Canada's donation and transplant system through recommendations to the Conference of Deputy Ministers of Health. The CCDT Donation Committee strategy is to develop a framework for action at local, provincial/territorial and national levels that will develop and incorporate best practices for organ and tissue donation as a routine part of end-of-life care. This framework is based on best evidence provided through a review of existing practices, policies or guidelines (national/international); a review of science and literature; and expert consensus.

To date, the CCDT Donation Committee has hosted two Forums to consult with health professionals and other key stakeholders on best practices that can inform the development of recommendations to the Conference of Deputy Ministers of Health:

- *Severe Brain Injury to Neurological Determination of Death: A Canadian Forum* held in April, 2003, which focused on development of a national agreement on the processes of care, commencing with severe brain injury and culminating with neurological determination of death. The final report on this initiative was released in October 2003.
- *Medical Management to Maximize Donor Organ Potential: A Canadian Forum* held in February, 2004, which developed guidelines and standards that will enable Canadian health professionals to improve the management of the organ donor to maximize donor organ potential. The final report was released in May 2005.

As the next step in this strategy, the CCDT Donation Committee convened a third Canadian Forum, “Donation After Cardiocirculatory Death,” sometimes described as Non-heart-beating Donation (NHBD). The focus of this Forum was to initiate a national multi-stakeholder discussion to inform and guide health care professionals involved in developing programs for donation after cardiocirculatory death. For the purposes of this Forum, a priori, the concept of organ and tissue donation after death was accepted, as it is a reflection of current practice; discussion at the Forum was restricted to optimal and safe practice in the field as it pertains to donation after cardiocirculatory death.

The recommendations in this DCD Forum report promote patient-care based principles for providing the option of donation within a sound ethical framework and provide guidance to individual programs in developing parameters of safe practice in this field.

We collectively thank the CCDT and collaborating organizations for their support for this initiative as well as the Canadian and international expert participants who helped to create these recommendations.

A handwritten signature in blue ink, appearing to read 'Sam D. Shemie', with a long horizontal flourish extending to the right.

Sam D. Shemie, MD  
Forum Co-Chair

## Executive Summary

These recommendations are the result of a national, multidisciplinary, year-long process to discuss whether and how to proceed with organ donation after DCD in Canada. The purpose of the national Forum held in February 2005 was to discuss and develop recommendations on the principles, procedures and practice related to DCD, including ethical and legal considerations. At the Forum's conclusion, a strong majority of participants supported proceeding with DCD programs in Canada. The Forum also recognized the need to formulate and emphasize core values to guide the development of programs and protocols based on the medical, ethical and legal framework established at this meeting.

While end-of-life care should routinely include the opportunity to donate organs and tissues, it is emphasized that the duty of care towards dying patients and their families remains the dominant priority of health care teams. The complexity and profound implications of death are recognized and should be respected, along with differing personal, ethnocultural and religious perspectives on death and donation. Decisions around withdrawal of life-sustaining therapies, management of the dying process, and the determination of death by cardiocirculatory criteria should be separate from and independent of donation/transplant processes.

The recommendations in this report serve to guide individual programs, regional health authorities and jurisdictions in the development of DCD protocols. Programs will develop based on local leadership and advance planning that includes education and engagement of stakeholders, mechanisms to assure safety and quality, and public information.

It is recommended that programs should begin with controlled DCD within the intensive care unit where (after a consensual decision to withdraw life-sustaining therapy) death is anticipated, but has not yet occurred, and unhurried consent discussions can be held. Uncontrolled donation (where death has occurred after unanticipated cardiac arrest) should only be considered after the controlled DCD program is well established. Although it is recommended that programs commence with kidney donation, it is recognized that regional transplant expertise may guide the inclusion of other organs. The impact of DCD, including pre- and post-mortem interventions, on donor family experiences, organ availability, graft function and recipient survival should be carefully documented and studied.

The first phase of implementation of these recommendations involves reporting to the Conference of Deputy Ministers of Health. The second phase depends on Forum Recommendation Group members, Forum participants, jurisdictional members of health care teams and provincial donation agencies to adapt and implement recommendations. Concurrently, endorsement by relevant professional societies and stakeholder organizations and journal publication will be pursued.



## Forum Committees

<b>Sam D. Shemie, MD Forum Co-Chair</b>	Division of Pediatric Critical Care, Montreal Children's Hospital, McGill University Health Centre Canadian Critical Care Society Canadian Council for Donation and Transplantation	Steering Committee Planning Committee
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<b>Andrew J. Baker, MD</b>	Medical Director, Trauma and Neurosurgery Intensive Care Unit, St. Michael's Hospital, University of Toronto Trillium Gift of Life Network Canadian Critical Care Society Canadian Anesthesiologists' Society	Steering Committee Planning Committee
<b>Janet Davidson</b>	Chief Operating Officer, Vancouver Acute, Vancouver Coastal Authority	Steering Committee
<b>John Dossetor, MD</b>	Professor Emeritus (Medicine/Bioethics), University of Alberta Canadian Society of Transplantation	Steering Committee
<b>Daniel Howes, MD</b>	Department of Emergency Medicine, Kingston General Hospital, Queen's University	Steering Committee
<b>Greg Knoll, MD</b>	Medical Director, Renal Transplantation, The Ottawa Hospital Canadian Society of Transplantation	Steering Committee Planning Committee
<b>Graeme Rocker, MD</b>	Professor of Medicine, Dalhousie University Critical Care Program, Queen Elizabeth II Health Sciences Centre, Halifax Past President, Canadian Critical Care Society	Steering Committee
<b>Dorothy Strachan</b>	Strachan-Tomlinson and Associates	Planning Committee Forum Facilitation
<b>William Wall, MD</b>	Director of Multi-Organ Transplant Program, London Health Sciences Centre Canadian Society of Transplantation	Steering Committee
<b>Kimberly Young, RN, BScN</b>	Chief Executive Officer, Canadian Council for Donation and Transplantation Canadian Association of Transplantation	Steering Committee Planning Committee

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### **Sponsored by:**

The Canadian Council for Donation and Transplantation

### **In collaboration with:**

The Canadian Critical Care Society

The Canadian Association of Transplantation

The Canadian Society of Transplantation

## Participating Organizations

- British Columbia Ministry of Health Services
- British Columbia Transplant Society
- Canadian Anesthesiologists' Society
- Canadian Association of Critical Care Nurses
- Canadian Association of Emergency Physicians
- Canadian Association of Neurology Nurses
- Canadian Association of Transplantation
- Canadian Bioethics Society
- Canadian Blood Services
- Canadian Council for Donation and Transplantation
- Canadian Critical Care Society
- Canadian Medical Association
- Canadian Medical Association Journal
- Canadian Neurological Society
- Canadian Neurosurgical Society
- Canadian Nurses Association
- Canadian Society of Transplantation
- Health Canada
- Human Organ Procurement and Exchange (HOPE) Program
- Manitoba Transplant Program
- Multi-organ Transplant Program – Nova Scotia
- New Brunswick Department of Health and Wellness
- Ontario Ministry of Health and Long-Term Care
- Operating Room Nurses Association of Canada
- Québec-Transplant
- Royal College of Physicians and Surgeons
- Saskatchewan Transplant Program
- Trillium Gift of Life Network



*Part I:*

**Forum Overview**

## Forum Overview

The purpose of this initiative was to discuss and develop recommendations on the principles, procedures and practice related to DCD within a sound ethical and legal framework in the context of protecting and serving the public. The fundamental question for the Forum was:

*Can we offer DCD while maintaining the fundamental principles that preserve patient and family<sup>1</sup> interests and professional standards?*

## Forum Objectives

1. Establish Canadian medical criteria for defining eligibility for organ donation after cardiocirculatory death.
2. Discuss conditions under which cardiocirculatory death, once anticipated or established, can activate organ donation procedures.
3. Explore the ethical implications of DCD including:
  - a. Defining death independent of the needs of organ donation/transplantation.
  - b. Interventions on patients prior to expressed or granted consent.
  - c. Interventions after consent.
  - d. Potential conflicts of interest.
  - e. Protecting and serving the public.
4. Address consent issues (e.g., related to timing and accountability for decision making).
5. Define the technical procedures and preservation techniques for organ donation and procurement.
6. Define reasonable time limits for solid organ donation to be successful, including discussion of evolving techniques to maximize the opportunity.

## Scope

The scope of the Forum included the interval from the anticipation and/or determination of cardiocirculatory death to organ recovery. The following issues were not included in the scope of this Forum:

1. Ethical considerations related to existing medical practice *did not* include the ethical framework for:
  - a. Withdrawal of life-sustaining therapy (WLST) in the intensive care unit (ICU): the medical decision to withdraw life support is within the domain of critical care practice. Discussion of WLST processes was limited to the manner in which they influence organ donation practice and organ viability.
  - b. Not initiating or terminating cardiopulmonary resuscitation.

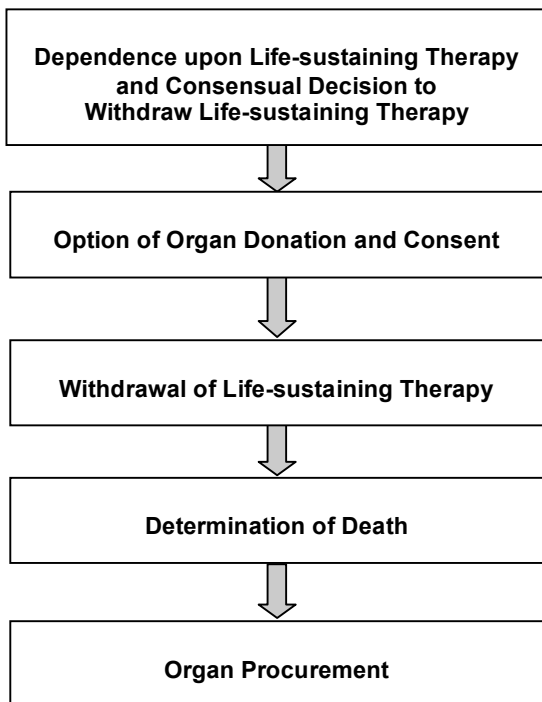
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<sup>1</sup> For the purposes of this document and forum recommendations, “family” is broadly defined to include those persons identified by the patient or client as providing familial support, whether or not they are biologically related. [Canadian Nurses Association (1997). *Nursing Now: Issues and Trends in Canadian Nursing*. September, adapted.]

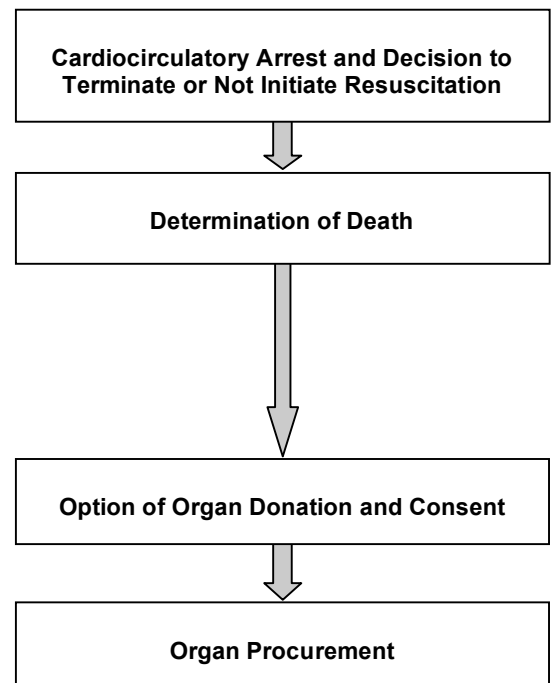
2. Ethnocultural and religious considerations regarding the cardiocirculatory determination of death from the perspectives of various communities were not addressed.
3. Details of *ex-situ* organ preservation were not included.
4. Issues related to organ allocation were not included.

## The Sequences of Care in DCD

### Controlled



### Uncontrolled



## **Fundamental Forum Principles**

The Forum Planning and Steering Committees developed, reviewed and approved the following principles to serve as a foundation for the Forum structure and discussions.

### **A. Duty of Care in the Context of Donation**

1. To ensure that patient interests are the first and foremost priority.
2. To support the family making decisions on behalf of the patient.
3. To provide the opportunity and process to actualize donation if desired by patient or family.

A major Forum challenge was how to accomplish A3 without compromising A1 and A2.

### **B. Death by Cardiocirculatory Criteria**

1. Death by cardiocirculatory criteria is determined according to accepted medical practice. A priori, the Forum accepts cardiocirculatory death as a medical and legal concept of death in Canadian society.
2. It was beyond the scope of this Forum to (re)define accepted medical practice for cardiocirculatory death beyond the context of DCD.

### **C. Donation after Cardiocirculatory Death**

1. With family or prior patient consent, individuals may donate organs and/or tissues after death has been determined.
2. The scope of the Forum was to consider/define the circumstances and processes for proceeding with organ donation after death by cardiocirculatory criteria.
3. The issues related to death and donation after death are principally related to the dignity of the dying process and the medical procedures after death.

## Process

Substantive background documents were provided by the Steering Committee in advance of the Forum, including comprehensive literature reviews and related practice surveys. Each topic area was addressed during the Forum using the following process:

1. Presentations by experts from international jurisdictions where DCD is currently practiced were followed by open plenary discussions. Participants then worked in small groups guided by worksheets that provided:
  - a. A summary of existing scientific evidence.
  - b. A summary of bioethical and legal implications.
  - c. A comparative summary of international DCD management guidelines.
  - d. Forum principles.
  - e. Key considerations.
  - f. A list of references.
2. Small group discussions focused on specific questions related to the processes of care. Forum questions explored:
  - a. Death and minimum criteria to proceed with organ donation (controlled and uncontrolled DCD).
  - b. Process and procedures for withdrawal of life-sustaining therapies as they pertain to DCD (controlled DCD).
  - c. Options for organ donation and consent processes (controlled and uncontrolled DCD).
  - d. Interventions related to phases of care (controlled DCD).
  - e. Post-mortem care and interventions (uncontrolled DCD).
  - f. Limits of organ viability (controlled and uncontrolled DCD).
  - g. Preservation techniques: organ specific (controlled and uncontrolled DCD).
3. Meetings of the Forum Recommendations Group (FRG) reviewed the results of small group and plenary discussions and developed consensus recommendations that were returned to plenary for further clarification and discussion.
4. Participants' suggestions for relevant research questions were gathered and summarized.
5. The Logistics and Knowledge Transfer Group considered issues related to logistics and knowledge transfer that were identified during the Forum.

Forum participants represented a broad range of disciplines ensuring that discussions were inclusive and involved multiple perspectives. Forum deliberations were thoughtful, dynamic and collegial as participants focused on building agreement on key challenge questions.

Members of the FRG panel came to unanimous agreement on recommendations to inform current and future practice. Potential research areas were also identified as well as logistical and knowledge transfer issues.



## Outcomes

Results of the Forum will be used to help achieve the following overarching CCDT outcomes:

- Provide Canadian health care providers with a framework for the development of DCD programs.
- Provide Canadians with the option of organ donation after death, as part of optimal end-of-life care.
- Increase the number of organs available for transplantation.

The decision to donate and procure organs after death is distinct and separate from decisions to stop any form of life-sustaining treatment or intervention.

DCD protocols should:

- a. Affirm patient welfare, promote patient and family choice, and avoid conflict of interest.
- b. Provide accurate and honest information to families in a compassionate manner by the most knowledgeable professionals available.
- c. Give uniform guidance on criteria for determination of death under these circumstances.
- d. Describe the sequence and nature of interventions for donation and organ procurement.
- e. Clarify issues of consent.

## Expert Speakers

Given the complexity of the social, medical, ethical and legal challenges related to donation after cardiocirculatory death, a substantial part of the Forum agenda was dedicated to presentations from family, patient and medical perspectives to enable participant learning and understanding. They are listed below in the order in which they appeared on the agenda.

### Challenge Address

Sam D. Shemie, MD                                  Challenge Address

### Dialogue #1: Family

Valerie McDonald                                  Family Concerns Related to End-of-Life Care and Donation

Susan McVey Dillon                                  A Mother's Perseverance in Changing Practice

### Dialogue #2: Health Care Professionals

Ann Thompson, MD                                  Donation After Cardiac Death: Concerns of Pediatric Intensivists at the Children's Hospital of Pittsburgh

Andrew Baker, MD                                  The Ethics of Saying No to Donation After Cardiocirculatory Death: Patient/Family vs. Health Care Professionals Perspectives

### Dialogue #3: Legal Considerations

Kathy O'Brien, LLB                                  Legal Issues Arising from Donation after Cardiocirculatory Death

### Dialogue #4: Transplant and Critical Care

Professor Gauke Kootstra, MD                                  The Non-Heart-Beating Donor: The Maastricht Perspective

Michael DeVita, MD                                  EOL Care and Donation after Death: The View from Critical Care

### Withdrawal of Life-Sustaining Therapy

Graeme Rocker, MD                                  The Gathering Storm? End-of-life Care and Donation After Cardiac Death

Anthony M. D'Allessandro, MD                                  Donation after Cardiac Death: Evaluation of Potential Candidates at University of Wisconsin Hospital and Clinics

### Interventions Related to Consent and Death

James Dubois, PhD, DSc                                  Ethical Issues in Controlled and Uncontrolled DCD

George Agich, PhD                                  Developing DCD Protocols: Some Lessons from Ohio

**Related Research: Policy, Practice and Knowledge Translation**

Bruce McManus, MD, PhD      Related Research and Knowledge Translation: How Might We Work Together?

**American and European Transplant Perspectives: Presentations and Panel**

Anthony M. D’Alessandro, MD      Donation after Cardiac Death: Results of Transplantation of the Kidney, Liver, Pancreas and Lung at the University of Wisconsin

Richard Hasz      Donation after Cardiac Death (DCD): Issues and Considerations from American Transplant Perspectives

Paolo Muiesan, MD      Liver Transplantation from Non-Heart-Beating Donors: UK Experience

José Ramon Nuñez Peña, MD      Spanish Transplant Perspectives in Uncontrolled DCD

Professor Gauke Kootstra, MD      Panel respondent

**Death and Donation: Vicarious Trauma**

David Kuhl, MD, PhD      Death and Donation: Iatrogenic Suffering, Moral Distress, Vicarious Trauma

## Forum Recommendations Group Members

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<b>Kimberly Young, RN, BScN</b>	Chief Executive Officer, Canadian Council for Donation and Transplantation  Forum Project Manager, Donation After Cardiocirculatory Death

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<b>Bill Barrable</b>	Provincial Executive Director, British Columbia Transplant Society
<b>Richard Hasz</b>	Vice President, Clinical Services Gift of Life Donor Program, Philadelphia, PA
<b>Leah Hollins</b>	Chair, Canadian Council for Donation and Transplantation
<b>Jim Kutsogiannis, MD</b>	Physician Organ Donor Leader, Alberta Health and Wellness  Canadian Critical Care Society
<b>Frank Markel, PhD</b>	President and Chief Executive Officer, Ontario Trillium Gift of Life Network



*Part II:*

**Recommendations Related to DCD**

## Recommendations Related to DCD

Forum discussions about fundamental principles and ethics led to the expression of several concerns and related discussions about the need to formulate and emphasize core values to guide the development of program protocols and new procedures related to DCD.

### Core Values and Ethics

The following core values provide a framework to guide deliberations in local programs with respect to the ethical implementation of recommendations in this report.

**a. Respect for the life and dignity of all individuals.**

All human life, regardless of its actual or perceived quality or its stage in the dying process, is deserving of respect. While it is generally seen as appropriate to use the human body as a source of tissues and organs to serve the well being of other human beings, the donor's body should always be treated with great care and respect. Decisions that are made about a human being must be guided by that individual's values and beliefs with respect to a meaningful life and death. The care of the dying patient must never be compromised by the desire to protect organs for donation or expedite death for the benefit of timely organ retrieval.

**b. Optimal end-of-life care that respects the holistic well being of the dying patient.**

The first responsibility of health care providers, regardless of the potential for donation, is to advance the well-being of the dying patient. This includes psychological, emotional and spiritual well-being in addition to physical well being.

**c. Respect for patient autonomy.**

Decisions about care at the end of life should be based on the known values and beliefs of the patient. These decisions should be consistent with what each patient understands to be a meaningful life and death. A meaningful death for patients may or may not include the ability or desire to provide organs to others.

**d. Support for the grieving family and loved ones.**

It is important to provide support for those about to be bereaved, whether or not organ donation occurs. Memories of a loved one's death remain with those left behind. Support for families and loved ones should continue through all phases of dying: before, during and after withdrawal of life-sustaining therapy.

**e. Public trust and avoidance of actual and perceived conflicts of interest.**

It is important to recognize and minimize possibilities for conflicts of interest that might occur in the setting of DCD. Conflicts of interest occur when those involved in providing health care have relationships with persons or organizations outside the healing relationship that may influence their actions, whether or not they believe these relationships actually affect their judgment. Conflict of interest should be differentiated from dual commitments or the congruence of interest that naturally arises when health care teams provide the opportunity to donate for those who may wish to do so.

Conflicts of interest may have a negligible or considerable effect on judgment. They may influence care at any stage in the process of organ and tissue donation and therefore should be identified. Failure to identify and disclose such conflicts may undermine the integrity of a program, and jeopardize public and professional trust.

**f. Respect for professional integrity.**

Those involved with end of life care, donation and transplantation are guided by their own values and beliefs and by the professional values and standards of practice as articulated by their respective professional organizations. Decisions in the context of DCD must not be influenced by considerations of professional loyalties, prestige, personal gain or by any actions that are in conflict with the pursuit of excellence in end-of-life care for the potential or actual organ donor.

## **Overarching Considerations**

- This Forum, and the participating organizations represented, supports efforts to incorporate donation into end-of-life care and to optimize organ and tissue donation in Canada.  
  
Individuals should be provided the option of organ donation after death and health care systems should establish the processes and procedures to provide this option.
- Donation services should be offered in the context of maintaining respect for the beliefs and values of the individuals involved. It is recognized that based on societal, cultural, religious and other personal beliefs, some individuals within families and within the health care team may have different views on the meaning and permissibility of organ and tissue donation after death as determined by neurological or cardiocirculatory criteria. If patients/families decline the opportunity to donate, their decision should be fully supported. Healthcare team members who do not support organ donation should seek the involvement of an alternate colleague in appropriate circumstances.
- The current law related to donation is subject to interpretation in the context of DCD. Current consent to treatment legislation has not addressed issues specific to this form of donation. Forum participants discussed the need for further legal review to address this issue.



Based on these overarching considerations, the Forum made the following recommendations:

## 1. Terminology and Patient Conditions

### 1.1 Terminology and Patient Conditions

We recommend that:

1. The term “donation after cardiocirculatory death (DCD)” be adopted to refer to this form of donation in Canada.
2. Controlled DCD refers to circumstances where donation may initially be considered when *death is anticipated, but has not yet occurred*. This may take place in an ICU or special care unit after a consensual decision to withdraw life-sustaining therapy. Prior to considering donation, the patient should be judged to have:
  - i. A non-recoverable injury/illness;
  - ii. Dependence on life-sustaining therapy (LST);
  - iii. Intention to withdraw LST; and
  - iv. Anticipation of imminent death after withdrawal of life-sustaining therapy (WLST).
3. Uncontrolled DCD refers to circumstances where donation is initially considered after *death has occurred, but was not anticipated*. This may occur in the emergency department, hospital wards, ICU/special care unit or pre-hospital locations. The deceased will have had a witnessed cardiocirculatory arrest of known duration and there should already be an established decision to terminate or not to initiate cardiopulmonary resuscitation (CPR).
4. Donor suitability be determined by many factors including age of the donor, co-morbid disease states, specific tests of organ function, and terminal donor events. Demographic and organ function criteria should be the same as for donors after neurological determination of death (NDD) and should be determined by individual transplant programs.
5. Potential DCD donors should be considered regardless of age, but it is recognized that many existing DCD programs have a greater restriction on age criteria than for donors after NDD. Strict age criteria should be determined by individual programs.

### Key Considerations

- A “consensual decision to WLST” is defined as a decision to WLST that has been agreed to by the patient/family and the treating health care team.
- DCD replaces but is synonymous with other terms such as non-heart beating donation, donation after cardiocirculatory determination of death or donation after cardiac death.

- This Forum has used the terms “uncontrolled” (regardless of location, cardiac arrest is unanticipated) and “controlled” (cardiac arrest is anticipated). These terms replace existing categorizations that include the Maastricht criteria.
- These terms should not be misunderstood to imply that “controlled or uncontrolled” is a reflection of professional behaviours or the organization of clinical services. The degree of ‘control’ refers to the temporal constraints and the opportunity for consent discussions in relation to death.
- For uncontrolled DCD, management is complicated by the fact that death is sudden and/or unanticipated and may not have occurred within the medical setting. As donation interventions should be initiated as soon as possible, the surrogate decision makers or advance directives may not be immediately available to provide consent.
- For controlled DCD, LST can be defined as ventilatory support and/or artificial airway support and/or hemodynamic support provided in the ICU or special care unit. Patient conditions may include, but are not limited to, severe brain injury of diverse etiology, end-stage neuromuscular failure, high cervical spinal cord injury and/or end-stage organ failure.
- For completeness, the Forum addressed both forms of DCD. However, in its conclusion, the Forum has recommended that programs initiate and establish controlled DCD prior to advancing with uncontrolled DCD (recommendation 9.2).

## **Evidence**

Recommendation 1.1: page 55.

## 2. Death and the Minimum Criteria to Proceed with Organ Donation

### 2.1 Death and the Minimum<sup>2</sup> Criteria to Proceed with Organ Donation

We recommend the following:

#### 1. Determination of fact of death

By law, for the purposes of a post-mortem transplant and as it applies to DCD, the fact of death shall be determined by two physicians in accordance with “accepted medical practice.” Physicians must be physically present to determine death.

#### 2. Conflict of interest

No physician who has had any association with a proposed transplant recipient that might influence their judgment shall take any part in the determination of death of the donor.

#### 3. Prohibition on participation in transplant

No physician who took any part in the determination of the fact of death of the donor shall participate in any way in transplant procedures.

#### 4. Determination of Cardiocirculatory Death

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

- a) Beginning with the onset of circulatory arrest, a 5 minute period during which the absence of palpable pulses, blood pressure and respiration must be continuously observed by at least one physician; and
- b) Death is determined by two physicians by documenting the absence of palpable pulses, blood pressure and respiration upon completion of this 5 minute period.

The physician present during the 5 minute period of continuous observation and who makes one of the determinations of death must be a staff physician with the requisite skill and training.

Monitoring to establish the fact of death is the priority during this period of observation. There must be no interventions to facilitate donation during this time period.

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<sup>2</sup> Minimum should not necessarily be understood as “minimal.” “Minimal” refers to the least possible that can be done and is an absolute value. “Minimum” refers to the lowest acceptable standard, which is a relative standard, often pitched above the minimal. The standard recommended by the Forum sets minimum criteria for proceeding with organ recovery.

## **Key Considerations**

- For the purposes of DCD, one of the physicians determining death must be a staff physician with full and current licensure for independent medical practice in the relevant Canadian jurisdiction. Physicians on an educational register (residents, fellows) may carry out the second determination.
- The legal time of death is the determination after the 5 minute observation period.
- The purpose of the 5 minute observation period is to confirm the irreversibility of cardiocirculatory arrest prior to organ procurement.
- Blood pressure is defined as an arterial pressure that generates anterograde circulation. The preferred method to confirm the absence of blood pressure is by arterial line monitoring.

## **Evidence**

Recommendation 2.1: page 58.

### **3. Process and Procedures for Withdrawal of Life-sustaining Therapy: Controlled DCD**

#### **3.1 Process and Procedures for WLST**

We recommend the following:

##### **Decision-Making Process for WLST**

1. The medical and ethical framework for WLST in the ICU falls within the domain of critical care and neurocritical care practice and must not be influenced by donation potential. It is the responsibility of the critical care and neurocritical care communities to ensure optimal and safe practice in this field.
2. Health care professionals responsible for the decision and procedure to WLST should:
  - a. Have the requisite skill and knowledge in the area;
  - b. Not have any association with the proposed transplant recipient that might influence judgment;
  - c. Be independent of transplant proceedings; and
  - d. Act in accordance with current end-of-life practice in the local ICU or special care unit.
3. The decision to WLST should be made prior to any discussion of organ and tissue donation that is initiated by health care providers. The organ donation/procurement/transplant team must not be involved in the decision to WLST.

##### **Procedures for WLST**

1. The management of the dying process, including procedures for WLST and sedation/analgesia/comfort care, should proceed according to existing ICU practice in the best interests of the dying patient and should not be influenced by donation potential.
2. Consideration for the dignity of the dying process should be guided by patient interests and the family's needs and desires.
3. The family should be provided with a clear explanation of their option to remain with the patient during WLST, at the time of death and beyond, as well as a full discussion of the variables that may impact on organ viability for successful donation.
4. The ICU/patient care team is responsible for all aspects of management during this interval of care leading to death. The organ donation/procurement/transplant team must not be involved in procedures of WLST or in the management of the dying process.

### 3.1 Process and Procedures for WLST (cont'd)

5. WLST is an accepted part of end-of-life care in most hospitals in Canada and proceeds in accordance with accepted medical/ICU practice. We recommend that ICUs establish policies and procedures that:
  - Are consistent with current practices; and
  - Apply to any/all patients where WLST is considered.These policies and procedures should be locally determined and may include a bioethics consultation and/or opinion by a second physician.

#### Key Considerations

- The quality of the decision-making process must not be influenced by the potential for DCD.
- When WLST is proposed and DCD may be considered, the decision to proceed with withdrawal of life-sustaining therapy should be inclusive, consultative, contemplative and appropriately timed.
- As it applies to palliative care, the principle of double-effect supports the administration of treatments with the intent to support patient comfort and alleviate suffering, even if there is a risk (foreseen but not intended) of hastening death.<sup>3</sup>

#### Evidence

Recommendation 3.1: page 62.

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<sup>3</sup> Also known as the doctrine of double-effect. For further discussion, see pages 55 and 62, as well as McIntyre, A. (2004). The Doctrine of Double Effect. *The Stanford Encyclopedia of Philosophy*, Edward N. Zalta (Ed.), at URL: <http://plato.stanford.edu/archives/fall2004/entries/double-effect/>.

### 3.2 WLST Requirements and Safeguards

For the purposes of DCD, we recommend that the following additional requirements or safeguards be in place for the WLST decision-making process and procedures:

- Established ICU or hospital policies and guidelines related to WLST, including bioethics input;
- Review of DCD case management and a periodic quality assurance process; and
- Planned staff debriefing on a regular basis.

#### Key Considerations

- Quality of patient care and decision making should be the same irrespective of whether donation is considered. Policies and procedures for WLST should be in place for both donation and non-donation cases.
- Support for health care professionals should be provided as required.

#### Evidence

Recommendation 3.2: page 62.

### 3.3 Donor and Recipient Care

In the ICUs of hospitals that perform transplants, there may be unavoidable times when a potential controlled DCD donor (prior to death) is cared for in the same unit as an end-stage organ failure patient who is a potential transplant recipient. Under these circumstances, we recommend that attending hospital staff caring for the recipient should be different than staff caring for the donor.

#### Key Considerations

- Attending staff is defined as the attending staff physician and bedside nursing staff.
- It is recognized that local realities regarding logistics, staffing and practicalities may make it difficult to follow this recommendation. However, hospitals or jurisdictions implementing DCD programs should be responsible to provide the support necessary to develop this capacity.

#### Evidence

Recommendation 3.3: page 62.

### 3.4 Maximum Time Limit from WLST to Death

We recommend that there be a maximum time limit from WLST to death beyond which organs will not be offered or procured; that is, if death does not occur within this period, organs will not be procured and ICU end-of-life care will continue.

This time limit should be 1 to 2 hours, but should be guided by individual organ-specific programs and individual donor factors.

#### Key Considerations

- Time limits are related to family factors and ICU/operating room (OR) logistics.
- Setting time limits enables clarity of expectations for families and staff.
- Time limits are congruent with organ viability limits in section 7 of these recommendations.

#### Evidence

Recommendation 3.4: page 62.

### 3.5 Estimation of Time to Death after WLST

We recommend that following consent specific to this procedure, a formal estimation of the time to death after WLST be made using tools such as, but not restricted to the Wisconsin Evaluation Tool. The tool may be used to:

- Determine eligibility to donate.
- Provide input to family discussions about likelihood for successful donation.
- Guide the preferred location for WLST.

#### Key Considerations

- This tool is not currently applied as a standard practice in the WLST in the ICU. It should be considered as a donor-based intervention with appropriate consent.
- The safety of the procedure should be considered before its application.
- The reliability of predictive tools is dependent upon patient conditions and the specific ICU actions and tempo of procedures during WLST.
- The tools are in evolution and should be adjusted based on continuing research.
- There are clinical conditions that do not require the use of predictive testing such as patients on extracorporeal life support, including artificial heart technology or previous documentation of apnea (for other indications).



## Evidence

Recommendation 3.5: page 62.

### 3.6 Location of WLST

We recommend that WLST should occur in the ICU or in the OR, with flexibility based on family preferences, institutional logistics, resources and facilities.

## Key Considerations

- The family should be given information about the impact of the location of WLST on potential for successful donation.
- Psychosocial, spiritual and bereavement support should continue to be provided for families regardless of the location of WLST.

## Evidence

Recommendation 3.6: page 62.

### 3.7 Transfer of Patients Prior to WLST

We recommend that a patient who fulfils eligibility criteria for controlled donation, at a hospital where DCD is not practiced or available, may be transferred prior to WLST to a hospital that performs controlled DCD. This should only occur with full informed consent of the patient or family and with full consultation and agreement of the receiving hospital.

## Key Considerations

- This recommendation is based on the principle of referring a patient to a hospital that provides a service not available at the source hospital and is specific to donation/procurement hospitals that provide DCD.
- Logistics and funding to support this activity should be provided by individual jurisdictions.
- Costs associated with transfers should not impose an economic burden on the family.
- The family should be aware that imminent death following WLST and/or organ donation may not occur despite the transfer.

## Evidence

Recommendation 3.7: page 62.

## 4. Options for Organ Donation/Consent: Controlled DCD

### 4.1 Option of Organ and Tissue Donation

We recommend that:

- a. The option of organ and tissue donation should be routinely provided to all potential donors/families. Distinct from common practice after the NDD, it is necessary to present the option of donation *prior* to the fact of death in controlled DCD.
- b. In centres that develop DCD programs, the option of organ and tissue donation should be *presented* to patients/families *after the consensual decision* to WLST but *prior to the act* of WLST. A discussion of donation options may occur at anytime if initiated by a patient/family request for information.
- c. The person or group who is best trained and most experienced should hold the consent discussions, based on local organizational or institutional practice.

#### Key Considerations

- A “consensual decision to WLST” is defined as a decision to WLST that has been agreed to by the patient/family and the treating health care team.
- The initial discussion about the possibility of donation should be distinguished from the discussion to obtain informed consent for donation.

#### Evidence

Recommendation 4.1: page 68.

### 4.2 Notification of Coordinators

For controlled DCD where the patient fulfils eligibility criteria for donation, it is necessary to involve a separate coordinator prior to death. We recommend that coordinators be routinely notified by the ICU team after the consensual decision to WLST but prior to the act of WLST.

#### Key Considerations

- This recommendation should be considered in the context of provincial legislation.

#### Evidence

Recommendation 4.2: page 68.

## 5. Interventions Relative to Phases of Care: Controlled and Uncontrolled DCD

From the bioethical and legal perspective, the relevant intervals of care are *before* death and *after* death. Based on Forum plenary discussions, the Forum Recommendations Group concluded that it is premature to be prescriptive in the details for each donor-based medical intervention. The timing and type of interventions may vary by region and with the introduction of new therapies over time. The Forum recommends the following parameters for safe practice in consideration of risk/benefit ratio.

### 5.1 Donation-based Interventions

We recommend the following:

1. **Before death (as defined by Recommendation 2.1)**, and as it applies to controlled DCD, the care of the patient is under the direction of the patient care team. Interventions to facilitate donation require the specific and informed consent of the patient/family for each intervention. Their purpose should be understood in terms of how they might improve successful donation after death. These interventions should not be intended to hasten death or otherwise harm the patient and should pose no more than minimal risk. Interventions should only be undertaken with consideration of risks and benefits.
2. **After death (as defined by Recommendation 2.1)**, and as it applies to controlled and uncontrolled DCD, interventions require only general consent to donation.
3. Surgical interventions related to cannulation and perfusion should only be carried out by the organ retrieval or transplant team.
4. Thrombolytic agents should not be administered prior to the fact of death.
5. Heparin should not be administered prior to death in cases of established or ongoing bleeding.
6. Vasodilators should not be administered prior to death in patients who are receiving vasopressor support.
7. Interventions that may re-institute cerebral perfusion and oxygenation after the fact of death should not be instituted.

### Key Considerations

- Benefit to the patient is interpreted as both i) therapeutic benefit to the patient and ii) realization of the donor's interests and wishes based on the desire and intent to donate.
- Where the medical team seeks consent for pre- or post-mortem interventions, the team must ensure that the proxy has appropriate (legal) authority to grant such consent. Consideration should be given to the legal authority granted by consent to treatment legislation, tissue/organ donation legislation and case law.

- DCD has not been directly addressed by existing law. The consent regime as it applies to DCD, especially related to pre-mortem interventions, needs to be examined on a jurisdiction-by-jurisdiction basis to identify gaps or ambiguities.
- When the patient is capable, informed patient consent is to be obtained.

## **Evidence**

Recommendation 5.1: page 69.

## **5.2 Responsibility for Pharmacologic Interventions Prior to Death**

We recommend that the ICU team, or the anesthesiologist caring for the potential donor in the OR, are permitted to administer pharmacologic donor-based interventions prior to death.

## **Key Considerations**

- Organ donation or transplant coordinators who are not part of the patient care team should not administer donor-based pharmacological interventions.
- ICU team members should use their professional discretion in carrying out such treatments. This recommendation does not obligate ICU team members to carry out treatments they consider against the best interests of the patient.

## **Evidence**

Recommendation 5.2: page 69.

## 6. Post-mortem Care and Interventions: Uncontrolled DCD

### 6.1 Consent Process

We recommend that:

1. The option of organ and tissue donation should be routinely provided *after* death in uncontrolled DCD to the families of potential donors.
2. The consent process (which should include the acknowledgement of expressed donor intent, the identification of appropriate legal surrogate and/or the consent or refusal of donation) should be dictated by provincial legislation and current medical and ethical practice.
3. Expressed donor intent is legally sufficient to proceed with donation in the absence of proxy consent. However, it is recognized that the psychosocial, emotional and spiritual meaning of the act of donation will influence the decision-making process with families, even in the presence of a signed donor card or other indication of intent to donate.
4. In the absence of expressed donor intent and family consent, interventions and procedures for donation should not proceed.
5. Given its complexity, the consent process should be led by the most experienced person who can obtain the requisite informed consent and who is not part of the transplant team.

### Key Considerations

- Expressed donor intent is legally considered as a valid form of consent and is defined as a signed donor card or donor registry in the absence of any reason to believe the consent had been withdrawn. It is acknowledged that there are ethical/moral considerations that may override the authority that the legal regime bestows.

### Evidence

Recommendation 6.1: page 73.

## 7. Limits of Organ Viability: Controlled and Uncontrolled DCD

Ischemic organ injury during normothermia, as a result of hypotension and hypoxemia prior to death and circulatory arrest after death, directly impacts on organ viability for transplantation and is a limiting factor in organ recovery for DCD. After the patient/family consents to controlled DCD, there are steps in the process which may preclude donation. For example, the duration of the dying process might exceed the upper limits of organ viability in the context of transplantation. During the interval of time from WLST to death, patients who experience a slow progressive demise (hypotension and hypoxemia) may become unsuitable candidates as organs can be irreparably damaged by warm ischemic injury during the dying process. In addition, there are time constraints related to logistical preparations involving the surgical procurement team members/anesthesia/operating room staff who must be alerted and on hold until death is established.

### 7.1 Warm Ischemic Time (WIT)

We recommend that warm ischemic time be defined as:

1. WLST initiation to cold perfusion in *controlled* DCD.
2. Cardiac arrest to cold perfusion in *uncontrolled* DCD.

Independent of definition and limits of WIT, we recommend that the following data and time points should be recorded for transplant purposes:

#### Controlled

1. The first action to WLST (e.g., weaning inspired oxygen).
2. The final action to WLST (e.g., extubation).
3. Urine output during WLST.
4. Systolic blood pressure first falls below 50% of baseline.
5. Oxygen saturation first falls below 80%.
6. Onset of circulatory arrest.
7. The 5 minute interval.
8. Determination of death (physician #1 and physician #2).
9. Cannulation begins (femoral or sterno-laparotomy).
10. Initiation of cold perfusion of organs.

#### Uncontrolled

1. Cardiac arrest to initiation of CPR.
2. Duration of CPR before death determination.
3. Determination of death (physician #1 and physician #2).
4. Initiation of cold perfusion of organs.

### **Key Considerations**

- The process of WLST varies among hospitals and ICU practitioners; the terminal events in the process of dying also vary among individual patients.
- Documentation of physiological events during WLST is important when organs may be used for transplantation.

### **Evidence**

Recommendation 7.1: page 76.

## **7.2 Maximum Time for Offering Organs**

We recommend that the maximum time beyond which organs should not be offered for controlled and uncontrolled DCD be determined by local transplant program protocol and experience.

### **Key Considerations**

- Current practice is approximately 2 hours (2 hours for kidneys, 1 hour for pancreas and lungs, 30 minutes for liver).
- Other variables important in the time limit include (but are not limited to) age and comorbidity of the donor and agonal events during WLST.

### **Evidence**

Recommendation 7.2: page 76.

## 8. Preservation Techniques: Controlled and Uncontrolled DCD

### 8.1 *In-situ* Techniques for Preservation

We recommend that the preferred *in-situ* technique for preservation in both *controlled* and *uncontrolled* DCD be determined by local transplant program protocols and experience.

#### Key Considerations

- This recommendation depends upon pre-mortem interventions (e.g., cannulation), surgical preferences (e.g., femoral cannulation versus sternolaparotomy) and logistics.

#### Evidence

Recommendation 8.1: page 78.

### 8.2 *Ex-situ* Kidney Storage

We recommend that machine pulsatile perfusion should be available at institutions offering DCD programs where kidneys must be stored *ex-situ*.

#### Key Considerations

- Although there have been no prospective studies comparing storage techniques, limited evidence suggests that machine pulsatile perfusion is the preferred organ preservation technique as it may permit viability testing and may enhance organ viability.

#### Evidence

Recommendation 8.2: page 78.





*Part III:*

**Overarching Recommendations  
for Jurisdictions**

# Overarching Recommendations for Jurisdictions

## 9. DCD Programs

### 9.1 Initiating a DCD Program

We recommend the following *prior to* initiating a DCD program:

1. Formal institutional approval within the existing hospital reporting structure.
2. An integrated, collaborative approach involving:
  - Consultation and involvement of hospital stakeholders [e.g., emergency department (ED), ICU, OR, risk management, pastoral care, bioethics].
  - Communication, information and education of staff (e.g., ED, ICU, OR, risk management, pastoral care, bioethics).
  - Communication, information and education of the public.
3. Established quality assurance procedures in organ/tissue programs after NDD and tissue donation after cardiocirculatory death.
4. Formal support/collaboration of the regional organ donation organization.
5. A risk management plan for DCD centres and partners.

We recommend the following to be in place to start an institutional DCD program:

1. Full time ED (for uncontrolled DCD) and ICU (for controlled DCD) facilities.
2. Established end-of-life care protocols.
3. Presence of an established and effective program in organ donation after NDD.
4. Availability of a procurement team.
5. Structured support from the regional Organ Procurement Organizations (OPO).

Measures should be taken to ensure that concerns (real and/or perceived) for the safety of patients and the public, protection of health care workers and/or preservation of the integrity of the donation system are safeguarded. These measures may include:

- Auditing by an independent organization (analogous to a Data Safety Monitoring Board, or Research Ethics Board) and/or internal health region/hospital based multidisciplinary group.
- Approval of programs by the regional coroners/medical examiners.

## 9.2 Initial Focus of a DCD Program

We recommend that:

1. Centres initiating a DCD program start with kidney donation and expand to include other organs as experience and expertise develop.
2. In their initiation phase, centres should proceed only with controlled DCD. Uncontrolled DCD should not be initiated in centers until controlled DCD programs are well established with demonstrated quality assurance.

### Key Considerations

- Site visits to centres with established programs are advisable.
- Expansion is dependent on local physician expertise and the development of related programs.
- Centres must have adequate quality assurance controls.
- Some centres may prefer to focus on any organs that may reasonably be used.

### Conclusion

A principal objective of this Forum was to discuss the ability to provide the opportunity and process to actualize DCD without compromising patient interests and family support. At the conclusion of the Forum, a strong majority of participants supported Canadian donation and transplantation programs in proceeding with DCD under the medical, bioethical and legal framework articulated and enabled by these recommendations. It is understood that these are recommendations for minimum standards. Individual regions or programs may adopt, adapt or consider additional standards as they apply to their health care environments.

## Recommendations for a National Research Agenda

Forum participants recognized that levels of evidence as they apply to DCD are largely based on regional experiences, retrospective studies and expert opinions. The Canadian Institutes of Health Research encourage partnerships in the development and funding of rigorous investigation to augment existing research.

The following areas for prospective research were identified during the course of forum discussions:

1. Reliability of clinical tools to predict time to death after withdrawal of life-sustaining therapy.
2. Impact of pre-mortem versus post-mortem interventions (e.g., heparin, phentolamine) on graft function and recipient survival.
3. The impact of DCD and warm ischemic time on graft function and recipient survival.
4. Mechanisms of apparent graft injury with DCD and strategies for amelioration.
5. Optimal techniques to assess organ viability.
6. Comparison of the use of cold storage versus machine pulsatile perfusion on graft function.
7. Meaning and impact on families who donate: a qualitative study.

## **Recommendations for Management and Administration**

### **Overarching**

The Forum recognized the importance of management and administration to enable implementation of policies and practices and in support of an effective and efficient DCD program. General recommendation themes that arose during forum discussions were:

### **Education**

Identify key stakeholders and target audiences and develop educational strategies; for example:

- Public and professional education.
- Ethnic and sociocultural issues.
- Advocacy role in supporting hospitals and regional health authorities for this initiative.
- Education for politicians and bureaucrats and advocacy with the public.

### **Ethics**

The opportunity to address ethical issues related to DCD and develop strategies for managing them; for example:

- Resources for bioethics support in hospitals and regional health authorities.
- Involvement of bioethics experts in the development of policies and guidelines.
- Public fora.

### **Leadership**

Identify and support key health leaders (physicians, nurses, ethicists, etc.) at all levels.

### **Policy and Practices**

Identify, develop and implement policies that support the implementation of DCD from the national level to the bedside; for example, through:

- National guidelines.
- Interjurisdictional policy alignment.
- Roles and responsibilities, policies and practices for health authorities and individual hospitals.

### **Resources**

Identify and provide required resources at federal/provincial/territorial/local levels; for example:

- Equipment.
- Manpower.
- Space (family-friendly environments).

## **Future Planning**

Overcoming administrative and managerial challenges depends on broad collaboration among jurisdictions such as Federal/Provincial/Territorial governmental and regional donation/transplantation agency representatives. It is recommended that an inter-jurisdictional working group address common management and administration issues to facilitate DCD in the future.



*Appendices*

## Appendix 1: Key Terms and Acronyms

### 1. Key Terms

#### Asystole

Asystole is complete cessation of cardiac function; that is, absence of systole and electrical activity.

#### Clinical Practice Guidelines

In 1994, the Canadian Medical Association adopted the definition of clinical practice guidelines (CPGs) as “... systematically developed statements to help practitioner and patient decisions about appropriate health care for specific clinical circumstances.” CPGs help physicians decide what is the most effective and appropriate intervention, while care maps help the health care team organize the delivery of the interventions.

Good clinical guidelines have three properties:

- First, they define practice questions and explicitly identify all their decision options and outcomes.
- Second, they explicitly identify, appraise and summarize, in ways that are most relevant to decision-makers, the best evidence about prevention, diagnosis, prognosis, therapy, harm and cost-effectiveness.
- Third, they explicitly identify the decision points at which this valid evidence needs to be integrated with individual clinical experience in deciding on a course of action.

#### Cold Ischemic Time

The interval between initiation of organ preservation and organ transplantation.

#### Dead Donor Rule

The “dead donor rule” refers to two widely accepted ethical norms that govern practices of organ procurement for transplantation:

- (1) Vital organs can only be taken from dead patients; and
- (2) Living patients cannot be killed for or by organ procurement.

It is generally assumed that a violation of these ethical norms would constitute euthanasia, violate state laws, and, therefore have legal consequences. [Adapted from Youngner, S. and Arnold, R. (1993). Ethical, Psychological, and Public Policy Implications of Procuring Organs from Non-Heart-Beating Cadaver Donors. *JAMA* 269: pp. 2769-74.]



## Evidence-based Medicine

Good clinical practice guidelines come from evidence-based medicine (EBM),<sup>4</sup> which is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

The five steps of EBM are:

- Convert clinical information needs into answerable questions.
- Track down the best evidence with which to answer them.
- Critically appraise that evidence for its validity (approximation to the truth) and usefulness (clinical applicability).
- Apply the results of this appraisal in clinical practice.
- Evaluate the clinical performance.

EBM can address each of the five clinical objectives of:

- Achieving a diagnosis.
- Estimating a prognosis.
- Deciding on the best therapy.
- Determining harm.
- Providing care of the highest quality.

## Family

For the purposes of this document and forum recommendations, “family” is broadly defined to include those persons identified by the patient or client as providing familial support, whether or not they are biologically related. [Adapted from Canadian Nurses Association (1997). *Nursing Now: Issues and Trends in Canadian Nursing*. September.]

## “Hands-off” Period

A “hands-off” period is a time interval after death during which no intervention may be performed on a patient’s body; also referred to as a “period of non-intervention.”

## Minimum versus Minimal

Minimum should not necessarily be understood as “minimal.” Minimal refers to the least possible that can be done and is an absolute value. “Minimum” refers to the lowest acceptable standard, which is a relative standard, often pitched above the minimal. The standard recommended by the Forum sets minimum criteria for proceeding with organ recovery.

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<sup>4</sup> An excellent resource for EBM is the Users' Guides to the Medical Literature by the Evidence Based Medicine Working Group. The series was published in *JAMA* 1993-2000 (bibliography) and is available from Centres of Health Evidence at: <http://www.cche.net/usersguides/main.asp>

## **Non-heart-beating Donation**

Non-heart-beating donation refers to the procurement of organs for transplantation from individuals who are declared dead according to the circulatory-respiratory criteria recommended in the Uniform Declaration of Death Act; also known as “donation after cardiac death (DCD)” or “donation after cardiocirculatory determination of death (DCD).”

## **Performance Measures**

Performance measures are methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality (Institute of Medicine, 1990).

## **Review Criteria**

Review criteria seek “to enable clinicians and others to assess care.” More specifically, the Institute of Medicine (IOM) suggests that they are “systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcomes.” To permit such assessments, the statements must usually be “suitable for retrospective medical record review of clinical practice” and capable of evaluating key pathways of past care, including guideline implementation.

Although clinicians and others may aim for excellence, review criteria frequently emphasize minimum thresholds of care. Moreover, according to Grimshaw and Russell, they should be “based on mandatory or, at worst, near mandatory elements.” Despite the IOM definition of review criteria, it is therefore important that these criteria assess appropriateness and necessity in order to show whether inappropriate and necessary care have taken place. Criteria describing appropriate care and unnecessary care are irrelevant to assessing minimum care and identifying service underuse and overuse.

## **Standards of Quality**

Standards of quality are authoritative statements of 1) minimum levels of acceptable performance or results, 2) excellent levels of performance or results, or 3) the range of acceptable performance or results (Institute of Medicine, 1990).

## **Uncontrolled versus Controlled Non-heart-beating Donation**

Uncontrolled non-heart-beating organ donation involves organ procurement from patients who experience unexpected circulatory arrest, and on whom CPR may be attempted but is not successful. Controlled non-heart-beating organ donation involves procuring organs from patients after their death in a planned withdrawal of life-sustaining therapy (DeVita et al., 2001). In both uncontrolled and controlled settings, death occurs when there is irreversible cessation of cardiac function [Glannon, W. (2005). *A Review of the Ethical Issues Surrounding Non-Heart-Beating Organ Donation*. CCDT: Edmonton.].

## **Warm Ischemic Time**

Warm ischemic time refers to the time interval between cardiac death and initiation of organ preservation. There may be practice variations between start times; for example, asystole, withdrawal of life sustaining therapy or predetermined vital thresholds. The end time is generally understood as initiation of cold perfusion. The definition of warm ischemic time has significant implications for organ viability for transplantation.

## 2. Abbreviations

ABG	Arterial Blood Gas
ACCCM	American College of Critical Care Medicine
AMS	Accepted Medical Standards
ARDS	Acute Respiratory Distress Syndrome
ATN	Acute Tubular Necrosis
BD	Brain Death
BP	Blood Pressure
CA	Cardiac Arrest
CABG	Coronary Artery Bypass Grafting
CAT	Canadian Association of Transplantation
CCCS	Canadian Critical Care Society
CCDT	Canadian Council for Donation and Transplantation
CDMH	Conference of Deputy Ministers of Health
CIHI	Canadian Institute of Health Information
CIHR	Canadian Institutes of Health Research
CIT	Cold Ischemic Time
CMA	Canadian Medical Association
CMAJ	Canadian Medical Association Journal
CME	Continuing Medical Education
CNS	Central Nervous System
CNS	Canadian Neurosurgical Society
CORR	Canadian Organ Replacement Register
CPR	Cardiopulmonary Resuscitation
CRI	Chronic Renal Insufficiency
CS	Cold Storage
CSN	Canadian Society of Nephrology
CST	Canadian Society of Transplantation
CT	Coaxial Tomography
CVA	Cerebrovascular Accident
CVP	Central Venous Pressure
DBTL	Double-balloon Triple-lumen (catheter)
DCD	Donation after Cardiocirculatory Death
DDE	Doctrine of Double Effect
DDR	Dead Donor Rule
DGF	Delayed Graft Functioning
DND	Donation after Neurological Death
DNR	Do Not Resuscitate

EC	Euro Collins
ECG/EKG	Electrocardiogram
ECLS	Extracorporeal Life Support
ECMO	Extracorporeal Membrane Oxygenation
ED/ER	Emergency Department/Emergency Room
EMD	Electromechanical Dissociation
EOL	End of Life
ESRD	End Stage Renal Disease
FRG	Forum Recommendations Group
GL	Guideline
GST	Glutathione S Transferase
HBD	Heart Beating Donor
HCP	Health Care Professional
HD	Hemodialysis
Hg	Mercury
HTK	Histidine-tryptophan-ketoglutarate
ICH	Intracranial Hemorrhage
ICP	Intracranial Pressure
ICRH	Institute of Cardiovascular and Respiratory Health
ICU	Intensive Care Unit
IOM	Institute of Medicine
IPF	Initial Poor Function (liver)
ISHLT	International Society for Heart and Lung Transplantation
ISP	<i>In-situ</i> Preservation/Perfusion
IV	Intravenous
LST	Life-sustaining Therapy
MAP	Mean Arterial Pressure
MD	Medical Doctor
ME	Medical Examiner
MEMODOP	Medical Management to Optimize Donor Organ Potential
MP	Machine Pulsatile Perfusion
MTID	Minimum Time Interval After Death
NDD	Neurological Determination of Death
NHB	Non-heart-beating
NHBD	Non-heart-beating Donation
NHBOD	Non-heart-beating Organ Donation
NIBP	Non-invasive Blood Pressure
NKF	National Kidney Foundation (US)
NTL	Netherlands

ODO	Organ Donation Organization
OPO	Organ Procurement Organization
OR	Operating Room
PEA	Pulseless Electrical Activity
PNF	Primary Nonfunction (liver)
PON	Period of Non-intervention
PT	Prothrombin Time
PTT	Partial Thromboplastin Time
RCPC	Royal College of Physicians and Surgeons of Canada
RCT	Randomized Clinical Trial
RI	Resistive Index
RT	Radiation Therapist
SBINDD	Severe Brain Injury to Neurological Determination of Death
SBP	Systolic Blood Pressure
SP	Spain
SPK	Simultaneous Pancreas-kidney
UDDA	Uniform Declaration of Death Act (USA)
UNOS	United Network for Organ Sharing
UW	University of Wisconsin
UPMC	University of Pittsburgh Medical Centre
VSA	Vital Signs Absent
WIT	Warm Ischemic Time
WLST	Withdrawal of Life-sustaining Therapy

## Appendix 2: Summaries of Evidence

### 1. Patient Conditions and Donor Eligibility

#### Controlled versus Uncontrolled Donors

For the purposes of this Forum and from a practical clinical perspective, it is useful to classify DCD into two subgroups:

**Uncontrolled:** The patient presents with an *unanticipated* cardiac arrest, regardless of location. Precise information on the time of cardiac arrest is required in order to estimate warm ischemic time that impacts directly on organ viability. It includes:

1. Dead on arrival to the emergency department (Maastricht category I).
2. Unsuccessful resuscitation in patients with cardiac arrest, which may occur in the emergency department, ICU, special care units or hospital wards (Maastricht category II).
3. Cardiac arrest following the NDD in the ICU (Maastricht Category IV).

The majority of uncontrolled NHBD worldwide are Category I and II patients and constitute the bulk of patients considered eligible for NHBD in continental Europe and Japan.

**Controlled:** Cardiac arrest is anticipated and, characteristically, these patients are:

1. Already being treated in the intensive care or special care unit environment;
2. Do not fulfill neurological criteria for death;
3. Require ventilatory, artificial airway and/or hemodynamic support;
4. Continuing medical care may be considered futile or treatment burden exceeds benefit; and
5. Death is anticipated to occur imminently upon WLST.

Patient conditions may include, but are not limited to, catastrophic brain injury of diverse etiology, cervical spinal cord injury and end-stage neuromuscular diseases. These patients (Maastricht category III) constitute the majority of identifiable NHBD in the U.S.

#### Eligibility Criteria for NHBD

As a general rule, eligibility criteria are similar to organ donation after the NDD and should be based on demographic, age and organ function criteria detailed in the previous CCDT Forum (Medical Management to Optimize Donor Organ Potential, February 2004). Patients with a history of intravenous drug abuse, sepsis or serious systemic infection, or active malignancies and high-grade brain tumours are excluded. Bacteremic patients are not necessarily excluded (Freeman et al., 1999). Patients with non-melanoma skin malignancies and some primary non-metastatic brain tumours may be eligible [Heineman et al., 1995 (Maastricht); Brook et al., 2003 (Leicester); Wood et al., 2004]. Hepatitis B, C or HIV contaminated organs may be transplanted into recipients already infected with these same viruses. Infections with human T-cell leukemia-lymphoma virus, systemic viral infection (e.g., measles, rabies, adenovirus), prion-related disease, and herpetic meningoencephalitis are contraindications.

## Donor Age

There has been no consensus as to age limits for donors after brain death or cardiac death. In the majority of series comparing DCD donors vs. donors after brain death, the mean age of the DCD donors tended to be less than the comparative brain death cohort. In a multi-center Japanese series of 706 kidney transplants from DCD donors, donor age greater than 55 had the largest negative impact on long-term allograft survival (Hattori et al., 2003). There is a strong relationship between donor age and delayed graft functioning (DGF) rates. Given that DCD donors have increased DGF rates, the combination of older age and DCD donors may result in the highest DGF rates, although this has not been well documented.

## International Survey

### Patient Conditions – Controlled DCD

IOM: patient is neurologically devastated and ventilator dependent

NTL: incurable disease, dependent upon life-sustaining treatment

UK: 2/4 - “withdrawal of TX (treatment) is being considered”

1/4 - “case by case basis, ventilated or on inotropic support”

1/4 - no information provided

US: 7/8 - non-recoverable injury/illness and dependent upon life-sustaining therapy

for 2 of these, injury is “severe neurological injury”

for 3 of these, form of dependence is “ventilator dependent”

Other conditions described in addition to above:

2/8 - “does not fulfill brain death criteria”

1/8 - do not resuscitate (DNR) order written

### Age Restrictions – Controlled DCD

IOM: no information provided in document

NTL: ≤ 65 yrs.

UK: 2/4 - 16 to 65 yrs.

1/4 - 1 to 65 yrs., evaluate on a case by case basis

1/4 - discuss all kidney/liver: generally, kidney ≤ 65 yrs.; livers < 70 yrs.; lungs < 55 yrs.

US: 6/8 - no information provided in document

1/8 - < 80 yrs.

1/8 - 1 to 55 yrs.

### Age Restrictions – Uncontrolled DCD

IOM: no information provided in the document

NTL: ≤ 65 yrs.

SP: ≤ 55 yrs.

UK: same as controlled, discuss all potential cases for kidney/liver: generally, kidneys ≤ 65 yrs.; liver < 70 yrs.; lungs < 55 yrs.

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## 2. Death and the Minimum Criteria to Proceed with Organ Donation

### Legal Criteria for the Determination of Death

#### Canada

There is no federal statutory definition of death in Canada and, therefore, no standard legal definition of death that applies across the country. As health care comes under provincial and territorial jurisdiction, each province/territory has a statute that governs organ/tissue donation. With the exception of Quebec, New Brunswick, the Northwest Territories and Nunavut, all provinces have legislation that includes provision for the determination of death for the purposes of post-mortem transplantation and can be paraphrased as follows:

1. Determination of death must be made by at least two physicians in accordance with “accepted medical practice.”
2. The physicians making the determination of death:
  - a. must not have any association with the proposed transplant recipient that might influence their judgement, and;
  - b. cannot participate in the transplant proceedings.

#### U.S.

The U.S. Uniform Determination of Death Act (UDDA 1981) specifies that death may be ascertained by the irreversible loss of all brain function (brain death/ determination of death by neurological criteria) *or* by the irreversible cessation of cardiorespiratory function.

### Medical Criteria for the Determination of Death

Provincial and territorial legislation does not outline what is meant by “accepted medical practice” or the tests or mechanisms that should be employed to determine death. The strict medical procedures for death determined by neurological criteria was established by a previous CCDT sponsored forum ([www.canadiancriticalcare.org](http://www.canadiancriticalcare.org)) and is available ([www.ccdt.ca](http://www.ccdt.ca)).

The UDDA specifies 3 criteria for death by cardiorespiratory criteria: 1) unresponsiveness; 2) apnea; and 3) permanent cessation of circulation. However, the UDDA has never provided criteria for the determination; death should be declared based upon current standards established by the medical community.

Outside of review articles on NHBD, the cardiorespiratory criteria for death are rarely mentioned in the literature. A literature review did not identify any studies examining the various methods of monitoring for cardiocirculatory function at or near the time of death.

## Irreversibility of Death

Until recently there was little need for the medical community to concern itself with the timing of a patient's death and the literature pertaining to this issue is scarce. In Canada, death is declared by physicians (or their delegates) and coroners/medical examiners. Less frequently, nurses with advanced specialization may declare death, particularly in remote service areas. The timing of this declaration following cardiopulmonary arrest has been largely irrelevant and remains unspecified. The vast majority of deaths in Canada occur in circumstances where organ donation is not a consideration (Canadian Institute for Health Information & Statistics Canada, 1995-2002).

However, when contemplating NHBD the duration of cardiocirculatory arrest becomes relevant as the organs will deteriorate rapidly following cessation of oxygenation and perfusion. Organ procurement must not precede the clinical declaration of death by either neurological or cardiocirculatory criteria. The Dead Donor Rule (Robertson, 1999) is upheld to avoid causing death by removing an individual's organs.

In the context of end-of-life care with potential NHBD, a decision has been made to withdraw, terminate and/or not initiate resuscitative measures. Of concern is the meaning of "irreversible," particularly when a decision to withhold/discontinue CPR has been made. Death requires irreversible stoppage, yet it is unclear whether that means the heart *could* not be started or merely *will not* be (Veatch, 2000). The IOM argues that irreversibility is defined by the absence of spontaneous recovery of cardiorespiratory function. Although controversial, there has been speculation that a phenomenon known as autoresuscitation may exist (spontaneous, transient resumption of cardiac function following cardiopulmonary arrest) (Institute of Medicine, 1997).

Addressing the ambiguity surrounding the term "irreversible" in its position paper on NHBD, the ethics committee of the American College of Critical Care Medicine (ACCCM) distinguishes between stronger and weaker interpretations of "irreversible" (DeVita et al., 2001). On the stronger interpretation, the heart cannot be restarted no matter what intervention is done, including CPR. On the weaker interpretation, circulation cannot be restored because CPR efforts have been refused by the patient (as a DNR order in an advance directive), by a surrogate decision-maker, or by the medical team because it is not medically indicated. The ACCCM group has recommended the weaker interpretation, with a reasonable observation time of between 2 minutes from cessation of cardiocirculatory functions with no spontaneous restoration of circulation, as recommended by the Pittsburgh Protocol, and 5 minutes, as recommended by the IOM. The ACCCM argues that no less than 2 minutes is acceptable and no more than 5 minutes is necessary when determining death for potential NHBD. Menikoff (2002) argues that irreversibility of cardiopulmonary functioning may not be guaranteed following a five-minute period of arrest and that portions of the dying person's brain may not have ceased functioning totally at this point. The forum literature review could not identify any evidence base for either Menikoff's arguments or the IOM position.

## International Survey of NHBD Protocols

### Clinical Criteria for the Determination of Death – Controlled/Uncontrolled DCD

Site	Criteria/Techniques
IOM	C: Cessation of cardiac function/EKG, arterial pressure monitoring, and unresponsiveness U: MD judgement per individual situation (current practice: 30 min. of unsuccessful CPR, 10 min. of absent heartbeat after CPR is stopped)
NTL	C & U: Irreversible and final cardiac arrest/NA*
SP	U: Irreversible cessation of cardiac function and spontaneous breathing: absence of central pulse or cardiac electric complex AND apneic AND CPR applied as per standard protocol (CPR ~ 30 min. or not if cause of CA is incompatible with life), AND temperature $\geq 32^{\circ}\text{C}$ . Always occurs in hospital.
UK1	Electrical asystole/EKG
UK2	Asystole, ventricular fibrillation or pulse less ventricular tachycardia/EKG
UK3	C & U: Irreversible loss of the capacity for consciousness and to breathe (without cardiac output long enough to ensure hypoxic injury to cerebral cortex and brainstem), normothermic/NA*
UK4	Absence of cardiac output and respiration, lack of response to supra-orbital pressure, pupillary and corneal reflexes, normothermic/ECG and intra-arterial BP monitoring
US1	Asystole +/- or pulse less electrical activity/Cardiac monitor
US2	Irreversible cessation of circulatory and respiratory function/ECG and arterial catheter
US3	NA*/NA*
US4	No detectable blood pressure, pulse or cardiac sounds/NA*
US5	Confirm correct EKG placement and 0 pulse and 0 blood pressure and apnoeic/EKG, arterial catheter or NIBP monitor
US6	Irreversible cessation of circulatory and respiratory functions/NA*
US7	Absent pulse pressure or cardiac contraction and apneic and unresponsive to verbal and tactile stimuli/EKG and arterial catheter
US8	Irreversible cessation of circulatory and respiratory functions/EKG and arterial waveform, if available

\* No information found in document.

U=uncontrolled, C=controlled. **All values are controlled unless otherwise indicated.**

**Interval of time prior to proceeding with organ recovery.**

<b>Interval of Time – Controlled/Uncontrolled DCD</b>		
<b>Site</b>	<b>Duration*</b>	<b>Period of Non Intervention ('hands off')</b>
<b>IOM</b>	5 min. duration (full consensus on “5 min. interval” not established and depends on further study and dialogue). (C)	
	10 min. duration, no period of non intervention (U)	
N TL	5 min. (C and U)	None (C and U)
SP	5 min. (U)	None (U)
UK1	2 min.	5 min.
UK2	2 – 5 min.	5 – 8 min.
UK3	5 min. (C and U)	5 min. (C and U)
UK4	5 min.	5 min.
US1	5 min.	None
US2	5 min.	NA**
US3	NA**	NA**
US4	None	5 min.
US5	5 min.	5 min.
US6	None	5 min.
US7	2 min.	None
US8	None	5 min.

\* Duration: minimum length of time clinical criteria must be present to determine death.

\*\* NA- no information found in document.

U=uncontrolled, C=controlled. All values are controlled unless otherwise indicated.

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### **3. Process and Procedures for Withdrawal of Life-sustaining Therapy: Controlled DCD**

#### **Role of the ICU Team**

Mortality rates of ICU patients in Canada range from 10-20% in adults and 3-5% in children. Death in the ICU will usually occur in one of 4 ways:

1. Patients are receiving full treatment, suffer a cardiac arrest, and an attempt at CPR is made but is unsuccessful.
2. Patients are receiving full treatment, suffer a cardiac arrest, but no attempt at CPR is made (DNR orders in place).
3. Some or all of full treatment is withheld or withdrawn, the patient suffers a cardiac arrest and no attempt at CPR is initiated.
4. Death is determined based on neurologic criteria (neurological determination of death/brain death).

The majority of deaths in neonatal, pediatric and adult intensive care are related to irrecoverable illness and are preceded by withdrawal and/or withholding of life-sustaining treatment. This is accepted ICU practice throughout the world, although there is considerable geographic variation. Where the burden of continued treatment far exceeds benefit, WLST takes place after discussion and consent/assent by the patient or the patient's surrogate. Reported WLST rates in single center Canadian ICUs range from 65% (Wood & Martin, 1995) to 79% (Hall & Rocker, 2000).

There is evidence for practice variation in the provision of end-of-life care in the ICU, related to patient factors such as disease acuity, presence or absence of advance directives, attitudes and ethnocultural beliefs. Variance can also be explained by physician factors such as age and experience, religious background, subspecialty or place of work (academic vs. community centre or open vs. closed ICU) (Keenan et al., 1998; Asch et al., 1999; Cook et al., 1999).

**Methods of WLST** are influenced by patient condition but may vary between individual physicians and ICU centers. Different approaches to withdrawal of mechanical ventilation have been cited (Rocker et al., 2004). WLST methods may include, but are not limited to, one or more of the following:

1. Terminal extubation (removal of mechanical ventilation and the artificial airway).
2. Rapid discontinuation of mechanical ventilatory support.
3. Terminal weaning (gradual decrease in mechanical ventilatory support with or without removal of the artificial airway).
4. Gradual weaning of hemodynamic supports.
5. Rapid discontinuation of hemodynamic supports.

There are no standardized procedures for WLST nor is there any intrinsically “correct” way to proceed or optimal duration of the process. Patient care during this phase must be directed to maintaining patient comfort and alleviation of suffering. The principle of double-effect supports the administration of treatments consistent with this intent, even if there is a risk (foreseen but not intended) of hastening death. The use of comfort medications may vary in type (analgesics, sedatives), dosage, strategy (proactive prevention of pain vs. reactive treatment of pain) (Hall & Rocker, 2000; Hall et al., 2004). Regardless of underlying disease, variation in methods of WLST and the use of comfort medication may consequently result in variability of the time from WLST to death.

It is widely agreed that patient care issues must be totally differentiated from those related to organ procurement. The decision to WLST must be made independently of any decision to donate organs for transplantation. Detailed discussions regarding organ donation and procurement should not be held until the decision to withdraw medical therapy has been made (Zawistowski & DeVita, 2003). Physicians involved in the initial patient care and WLST as the patient dies must not be involved in the procurement and transplantation processes. This avoids both real and perceived conflicts of interest for ICU staff between their therapeutic duty to the critically ill patient and their non-therapeutic relationship to potential organ transplant recipients (DeVita et al., 2001; Snell et al., 2004). Under the circumstances where the ICU may concurrently care for end-stage organ failure patients who are potential transplant recipients, physicians and caregivers who may be in conflict should voluntarily withdraw from the care of a potential donor.

Once a decision to WLST has been made between the treating team and the family, approaching families about donation is ethically appropriate and consistent with a process that would enable patients or their substitute decision-makers to realize the patient’s desire and intent to donate organs after death. Some families might perceive the request for donation to imply that the principal concern of the medical team is with the patient’s organs rather than with the patient. It may be appropriate to delegate these discussions to representatives from an organ procurement organization and/or a program representative from the health care organization itself.

### **Predicting Death**

The WLST does not necessarily lead to imminent death. ICU practitioners are cognizant of the difficulty to reliably predict if and when a patient will die after WLST. Although no formal testing generally occurs (outside of NHBD), variables of influence include:

1. Patient conditions (e.g., level of consciousness, degree of airway obstruction, ventilatory drive, oxygenation impairment, hemodynamic instability).
2. Methods of WLST - procedures and comfort medications.

After the family consents to controlled DCD, there are steps in the process which may preclude donation; for example, the duration of the dying process might exceed the upper limits of organ viability in the context of transplantation. During the interval of time from WLST to death, patients who experience a slow progressive demise (hypotension and hypoxemia) may become unsuitable candidates for NHBD as organs will be irreparably damaged by warm ischemic injury during the dying process (Zwiatowski & DeVita, 2003). In addition, there are time constraints related to logistical preparations that include the surgical procurement team and anesthetist/OR staff who must be alerted and on hold until death and minimum criteria to donate are established.

A clinical tool developed by the University of Wisconsin program has predicted, with 90% accuracy, those patients who will expire within 2 hours following WLST (Lewis et al., 2003). The testing protocol collected information that includes patient age, airway status, vasopressor and inotrope therapy, and the respiratory status following 10 minutes of disconnect from the ventilator (respiratory rate, tidal volume, negative inspiratory force, blood pressure, pulse and oxygenation saturation). Selection of candidates for organ donation is predicated on the respiratory drive assessment and the use of this predictive tool prior to WLST. The Wisconsin experience would suggest that about 10% of potential DCD donors were returned to the unit or hospital floor for palliative care (Cooper et al., 2004).

## **The Role of the Operating Room**

WLST traditionally occurs within the ICU environment. Access to a surgical suite is typically required for organ procurement in controlled DCD, often necessitating transfer of the patient to the OR prior to WLST, allowing for rapid surgical intervention for organ preservation and procurement after death. Concerns have been cited about involvement of third party anesthesiologists during withdrawal of life-sustaining measures, particularly if they have not been previously involved with the care and WLST discussions specific to that patient (Van Norman, 2003; Truog, 2003). In most cases, it will be in the best interests of the patient/family for the ICU treating team to continue to assume responsibility for the dying process regardless of the location of WLST.

## **International NHBD Protocol Survey: Decision-making Process for WLST**

### **Process of Decision to WLST – Controlled DCD**

IOM: “the donation team should not be involved in making the decision to stop treatment or in setting the criteria for this decision. It should be based on patient and family choice and on established clinical ethical and legal guidelines”

NTL: no information provided in document

UK: 2/4 - “multi-disciplinary consensus with family”

1/4 - unit policy

1/4 - no information provided in document

US: 5/8 - no information provided in document

2/8 - “patient/immediate family discussion with attending MD”

1 included "Advance Directive by patient"

1/8 - “must be reviewed with medical examiner”

### **Timing/Independence of Decision to WLST – Controlled DCD**

IOM: “the decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation”

NTL: “strict separation of MDs caring for potential recipients from this”

UK: 3/4 - “prior to/independent of organ donation decision”

1/4 - unit policy

US: 8/8 - “prior to/independent of organ donation decision”

**Protocol to WLST Required – Controlled DCD**

- IOM: “should follow established protocols for withdrawing support and providing terminal care”
- NTL: no information provided in document
- UK: 3/4 - unit/hospital policy  
1/4 - no information provided in document
- US: 4/8 - protocol/GL/predetermined plan  
4/8 - no information provided in document

**International NHBD Protocol Survey: Procedures for WLST**

**Terminal Care/Comfort Measures during WLST – Controlled DCD**

- IOM: “determined by patient care team and hospital protocols. The withdrawal of support should be the same whether the patient will become a donor or not. Comfort measures should never be withheld”
- NTL: no information provided in document
- UK: 3/4 - provide comfort measures  
1 - treat discomfort/distress  
1 - prevent discomfort/distress  
1/4 - no information provided in document
- US: 7/8 - standard care/as per protocol  
1 - titrate to relieve distress  
1/8 - morphine requires consent

**Family Presence at WLST – Controlled DCD**

- IOM: “family preference”
- NTL: yes
- UK: 3/4 - yes (1-strict limitations)  
1/4 - unit policy
- US: 6/8 - yes  
5 - either location  
1 - “very rarely in OR which requires careful planning and designated individual to provide support”  
2/8 - no information provided in document

**Time Limits for “WLST to Death Interval” – Controlled DCD**

- IOM: no information provided in document
- NTL: no information provided in document
- UK: 1/4 - kidney 3 hrs., liver 2 hrs.  
“up to consultant transplant surgeon/coordinator”  
1/4 - kidney 3 hrs., liver and lung 1 hr.  
1/4 - 2-3 hrs. (not specific to organs)  
1/4 - decision of surgical team



- US: 4/8 - 60 min.  
1 - “or time frame determined by team and OPO”  
1 - “or a predetermined time after WLST”  
1/8 - 90 min.  
1/8 - 120 min.  
1/8 - “that is acceptable to OPO”  
1/8 - no information provided in document.

#### **Assessment to Predict “WLST to Death Interval” – Controlled DCD**

- IOM: no information provided in document  
NTL: no information provided in document  
UK: 3/4 - no information provided in document  
1/4 - level of cardiorespiratory support as a predictor of time to asystole  
US: 4/8 - no information provided in document  
2/8 - recommends testing to predict likelihood of asystole within time limits  
1/8 - “all pertinent testing” and has tool for this test  
1/8 - “respiratory evaluation”

#### **Location of WLST – Controlled DCD**

- IOM: ICU, OR or pre-op holding area, “flexibility per family wishes and needs”  
NTL: ICU or OR (most often in ICU)  
UK: 3/4 - ICU  
2/4 - OR (1 - exceptional cases in OR only to meet needs of family, not to decrease WTI)  
1/4 - decision with family and ICU staff  
1/4 - unit policy  
US: 8/8 – OR (2 - prefer OR, 1 - must test to predict asystole)  
5/8 - ICU (1- case by case, 1 - requires cannulation)  
3/8 - OR “holding/side room” (1 - requires cannulation)  
1/8 - family decision  
1/8 - other

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- Wood GG, Martin E. (1995). Withholding and withdrawing life-sustaining therapy in a Canadian intensive care unit. *Can J Anaesth* 42(3):186-91.

#### **4. Option of Organ Donation/Consent: Controlled DCD**

In controlled DCD, a competent patient or their surrogate has consented to the withdrawal of ventilation or other life-sustaining therapy. Consent implies that the patient or substitute decision-maker has been informed of the nature and purpose of the treatment withdrawal and understands what this action entails. Consent to organ procurement for transplantation is given by a patient or surrogate independently of consent to withdraw life-support and presumes that procurement will take place only after death has been declared. Life-support can justifiably be withdrawn and organ procurement commenced after a clinical declaration of death (Youngner et al., 1999). Withdrawal of life-support and subsequent organ procurement are permissible provided that the patient has been deemed imminently and irreversibly dying and has consented separately to the withdrawal of life-support and to organ procurement for transplantation (Truog, 1997).

#### **International Survey of NHBD Protocols**

##### **When to Offer Organ Donation and Request Consent – Controlled DCD**

IOM: after the decision to discontinue support or when the family asks about donation

NTL: no information provided in document

UK: 4/4 - after decision to WLST

US: 8/8 - always after decision to WLST

#### **References**

Truog R. (1997). Is it time to abandon brain death? *Hastings Center Report* 27: pp. 29-37.

Youngner SJ, Arnold RM, DeVita MA. (1999). When is death? *Hastings Center Report* 29: pp. 14-21.

## 5. Interventions Relative to Phases of Care: Controlled and Uncontrolled DCD

### Pharmacotherapy: Anticoagulants, Vasodilators, Thrombolytics

**Heparin** is administered as an anticoagulant to prevent thrombotic obstruction of blood vessels that can occur after the arrest of circulation. Heparin may be associated with bleeding risk and is contraindicated in the presence of active bleeding. **Phentolamine** is a vasodilator (blood vessel relaxant) intended to enhance organ blood flow. Phentolamine may be associated with a transient decrease in blood pressure. **Streptokinase** is a thrombolytic agent that dissolves existing clots that may interfere with organ perfusion and is associated with a higher risk of bleeding than heparin.

In order to be effective, intact circulation (prior to death) is required for systemic distribution, although some centers administer them after death in the preservation solution. Ethical concerns are related to therapies that have no direct benefit to the patient, and where there is a theoretical but small risk. Practice is not uniform and no trials have been done to evaluate dosage, timing of administration (pre-mortem vs. post-mortem) or impact on transplantable organ function. . Although not proven, pre-morbid heparin administration may lower the PNF and DGF rates. IOM recommends full disclosure in consent discussions.

Ethical concerns have been addressed in the U.S. and all DCD programs administer heparin prior to death and often prior to WLST. Phentolamine use is less common and the use of streptokinase is in early evolution and not well established. Many, but not all, European countries have followed the Maastricht policy precluding the use of medication that is not beneficial to the patient until after death (Sudhindran et al., 2003; Koffman et al., 2003).

### Re-establishment of Circulation following Death

Following declaration of death some centers may also choose to re-introduce cardiopulmonary support in an effort to provide some degree of perfusion of targeted organs and oxygenation of the lungs. These measures may include re-intubation and cardiac compressions (manual or machine) or extracorporeal membrane oxygenation. Although primarily applied to uncontrolled DCD, some centers are in the early phase of using extracorporeal membrane oxygenation in controlled DCD. This review could not find any evidence-base for any of these interventions. Medical and ethical concerns are related to the timing of re-establishing cerebral blood flow after cardiac arrest with unclear, but concerning implications on neurological function.

### Access for *In-situ* Preservation

Vascular access is required for administration of cold preservation solution to maintain organ viability after death and may be secured by femoral vessel cannulation or directly by sternolaparotomy. Staged preparation for *in-situ* preservation may include:

1. Sterile preparation and draping of the surgical field.
2. Isolation of femoral vessels by surgical cutdown.
3. Cannulation of vessels.

**The Doctrine of Double Effect** acknowledges that the same act can have both good and bad effects and consists of four conditions:

1. The action must be intrinsically good, independent of its consequences;
2. Although the bad effect of the action can be foreseen, the agent must directly intend only the good effect;
3. The bad effect must not be a means to the good effect; and
4. The good effect must be proportional to, compensate for, or outweigh the bad effect.

In many DCD programs, it is permissible to perform interventions on the patient to preserve the option of donation for the family, maximize the potential for useable organs or improve the function of organs once transplanted. If the intention is not to hasten the death of the donor but to preserve the organs to provide benefit to the recipient, then the doctrine of double effect can potentially apply (Veatch, 2000).

These interventions may include:

- i. Blood testing and relevant investigations for donor eligibility (ABO type, HLA-typing, virology screen, organ function evaluations).
- ii. Preparation for vessel cannulation.
- iii. Isolation/exposure of vessels for cannulation.
- iv. Vessel cannulation for *in-situ* perfusion.
- v. Administration of anticoagulants (heparin).
- vi. Administration of vasodilators (phentolamine).
- vii. Administration of thrombolytic agents (streptokinase).
- viii. Extracorporeal oxygenation and circulation.
- ix. *In-situ* perfusion with cold preservation solution.

In controlled DCD (dependent on which intervention) these interventions may occur:

- a. Prior to WLST.
- b. After WLST, but prior to death.
- c. In the interval between the onset of cardiocirculatory arrest and the formal determination of death.
- d. After the determination of death.

When discussing whether these interventions are permissible, it is important to consider:

- a. Evaluation of benefit; that is, does it contribute to successful donation.
- b. Evaluation of foreseeable harm/risk:
  - i. Interventions that do not involve greater than minimal harm/risk and thus do not require detailed consent.
  - ii. Interventions that involve a minor increase over minimal harm/risk and thus require detailed consent.
  - iii. Interventions that involve a significant increase over minimal harm/risk and thus should not be offered.

## International Survey of Practice

Seven out of 8 U.S. centres administer heparin prior to death.

## Expert Speaker Survey of Practice

### Interventions For Controlled NHBD

Legend:

DA – Anthony D’Alessandro, Madison WI

DE – Michael DeVita, Pittsburgh PA

HA – Richard Hasz, Philadelphia PA

KO – Gauke Koostra, Maastricht NL

MU – Paolo Muietan, London UK

NU – José Ramo Nuñez Peña, Madrid SP

Interventions For Controlled NHBD	Intervals Of Care			
	Prior to WLST*	After WLST* Prior to Death	After Death	After Death and “Hands off period” (if applicable)
1. Blood testing for donor eligibility	DA, DE, HA, KO, MU	-	-	MU (in some cases before perfusion, to avoid procedures not in best interest of pt)
2. Preparation for vessel cannulation	DA, DE	-		HA, KO, MU
3. Isolation/exposure of vessels for cannulation	DA, DE		DE <sup>#</sup>	HA, KO, MU
4. Vessel cannulation	DE	DA <sup>##</sup>	DA, DE <sup>#</sup>	DA, HA, KO, MU
5. Administration of anticoagulants (e.g. heparin)	DA (20-30,000 U) HA (300 U/kg)	DE (50,000 U)	-	MU
6. Administration of thrombolytics (e.g. streptokinase)	-	-	-	MU, DA
7. Administration of vasodilators (e.g. phentolamine)	DA 10-20 mg	-	-	-
8. Extracorporeal oxygenation and circulation	-	-	-	-
9. <i>In situ</i> perfusion with cold preservation	N/A <sup>**</sup>	N/A <sup>**</sup>	DE <sup>#</sup>	DA, HA, KO, MU
10. Other Medications	DA (methylpredisone 1 gm iv, N-acetylcysteine 10 gm iv, Vit E 1000 U iv all given ~2-4 hrs prior to WLST*)			
11. Other Interventions	-	-	-	-

\*WLST = withdrawal of life sustaining therapy, \*\*N/A=not applicable, #does not have a “hands off” period,  
##arterial pressures and saturations indicate patient will expire.

## References

- Sudhindran S, Pettigrew GJ, Drain A, et al. (2003). Outcome of transplantation using kidneys from controlled (Maastricht category 3) non-heart-beating donors. *Clin Transplant* 17(2):93-100.
- Koffman G, Gambaro G. (2003). Renal transplantation from non-heart-beating donors: a review of the European experience. *Journal of Nephrology* 16(3):334-41.
- Veatch R. (1992). *Death, Dying, and the Biological Revolution*, second edition. New Haven, CT: Yale University Press.
- Veatch R. (2000). *Transplantation Ethics*. Washington: Georgetown University Press.

## 6. Post-mortem Care and Interventions: Uncontrolled DCD

For uncontrolled DCD, the deceased has had a witnessed cardiocirculatory arrest of known duration and there should already be an established decision to terminate or not to initiate CPR. Management of uncontrolled NHBD is complicated in that death is unanticipated and medical teams are unprepared for commencement of *in-situ* preservation. When death is sudden and/or unexpected, the deceased often do not have their relatives/surrogate decision makers with them and advanced directives may not be immediately available. Ideally in North America, informed consent prior to donation-based interventions should be sought. However, the wishes of the deceased may or may not be known and next of kin may be absent. Some jurisdictions, including some American states, have adopted laws which allow for *in-situ* preservation without consent (District of Columbia DC ST, 2002; Florida Statutes, 2002; Virginia State Code, 2002). There are time constraints on how long these interventions can be applied, and it is possible that consent may not be available in a timeframe that allows organ procurement. Despite legalization of these interventions, serious ethical questions regarding the appropriate conduct of physicians at the time of death remain an issue. Possible interventions include:

- i. Blood testing for donor eligibility (tissue typing, cross match, virology screen).
- ii. Vessel cannulation.
- iii. *In-situ* perfusion.
- iv. Administration of anticoagulants.
- v. Administration of vasodilators (phentolamine).
- vi. Administration of thrombolytic agents (streptokinase).
- vii. Re-institution of chest compressions, mechanical ventilation.
- viii. Extracorporeal circulation and oxygenation.

There are two schools of thought on the issue of *in-situ* preservation without prior consent. Minimization of WIT preserves organ post-transplant function and provides the family with an opportunity to consider the merits of organ donation in a less hurried and somewhat less stressful environment. Given more time to consider the option, family support for NHBD has been shown to dramatically increase if cannula insertion occurs before, rather than after, family consent (DeVita et al., 1993). Nonetheless, ethical questions may arise when medical interventions are performed in the absence of prior informed consent from the deceased and/or the family. US public surveys have shown that 74% of respondents opposed allowing physicians to proceed with intravascular cannulation without prior consent (Seltzer et al., 2000). Many authors do not support these interventions, arguing that dignity for the dead is undermined by the unilateral decision of medical caregivers to proceed with these interventions.

In some uncontrolled DCD programs, it is permissible to perform interventions on the deceased to preserve the option of donation for the family, to maximize the potential for useable organs or improve the function of organs once transplanted. To achieve these goals, the interventions may need to be started prior to the availability of family consent.

When discussing whether these interventions are permissible, it is important to consider the ethical justifications for intervening on a dead body to preserve options of the family for donation, respect for the body, principles of consent and the legal implications.



## Re-establishment of Circulation following Death

Following declaration of death, some centres may also choose to re-introduce cardiopulmonary support in an effort to provide some degree of perfusion of targeted organs and oxygenation of the lungs. These measures may include re-intubation and cardiac compressions (manual or machine) or extracorporeal membrane oxygenation. These interventions are primarily applied to uncontrolled DCD in Spain. This review could not find any evidence-base for any of these interventions. Medical and ethical concerns are related to the timing of re-establishing cerebral blood flow after cardiac arrest with unclear, but concerning implications on neurological function.

## Legal

Under organ/tissue donation legislation, there is no *legal* reason for the family/proxy to be asked for consent when there is:

1. A valid consent from the deceased donor; and
2. No reason to believe the consent has been withdrawn.

Many physicians are unaware that the law gives them the authority to act on a signed donor card or other documented intent to donate and this is sufficient *legal* authority to retrieve organs after death. This applies in the absence of available family consent or in the face of family opposition. The proxy has no legal authority to give or refuse consent in the face of valid donor consent. It is recognized that in actual clinical practice, there are ethical, moral and family-based considerations that may override the authority that the legal regime bestows.

There are potential legal consequences of donation-based interventions after death in uncontrolled DCD *in the absence of preceding patient or family consent*. Under the *Criminal Code*, there is a potential for criminal liability when there is an offence of interference with a dead body (“improperly or indecently interferes with or offers any indignity to a dead human body or human remains, whether buried or not”).

## Expert Speaker Survey

Legend:

HA – Richard Hasz, Philadelphia PA

KO – Gauke Koostra, Maastricht NL

NU – José Ramo Nuñez Peña , Madrid SP

Legend (a) Yes, *prior* to family consent  
 (b) Yes, with informed, intervention-specific consent  
 (c) Yes, with coroner's consent

**Table 3 Interventions For Uncontrolled NHBD**

Interventions For Uncontrolled NHBD	Intervals Of Care	
	After Death	After Death and "Hands off period" (if applicable)
1. Blood testing for donor eligibility	HA(b)*, KO (a), NU(a)	HA(b)
2. Vessel cannulation	HA(b)*	HA(b), KO(a), NU(a)
3. In-situ perfusion with cold preservation	HA(b)*	HA(b), KO(a)
4. Administration of anticoagulants (e.g., heparin)	HA(b)* 300 U/kg	HA(b) 300 U/kg, NU(c) 500 U/kg
5. Administration of vasodilators (e.g., phentolamine)	-	-
6. Administration of thrombolytics (e.g., streptokinase)	-	-
7. Chest compressions, mechanical ventilation	HA(b)*	HA(b), NU (a)
8. Extracorporeal oxygenation and circulation	-	NU (c)
9. Other medications	-	-
10. Other interventions	-	NU (c) (lungs topical cooling)

\*HA(b): no hands off period for Maastricht Category 4 only

## References

DeVita, M., J. Snyder, et al. (1993). History of organ donation by patients with cardiac death. *Kennedy Institute of Ethics Journal* 3: 113-29.

Seltzer, D., R. Arnold, et al. (2000). Are non-heart-beating cadaver donors acceptable to the public? *The Journal of Clinical Ethics* 11: 347-56.

## 7. Limits of Organ Viability: Controlled and Uncontrolled DCD

### Warm Ischemia Time

Ischemic organ injury during normothermia, as a result of hypotension and hypoxemia prior to death, and circulatory arrest after death, directly impacts on organ viability for transplantation and is a limiting factor in organ recovery for DCD. This organ injury can be delayed by the use of hypothermia and preservation solutions. Definitions of WIT in controlled DCD vary in the literature; they have been defined as the time:

1. From cardiocirculatory arrest → cold perfusion of the organs; or
2. A fall in physiological parameters (blood pressure and oxygenation) below a predetermined level → cold perfusion of the organs; or
3. From WLST → cold perfusion.

Although there is general agreement that WIT should be minimized, various allowable time limits for WIT related to kidney transplantation have been recommended, most ranging from 30 to 45 minutes (Orloff, Reed et al. 1994; Light, Kowalski et al. 1996; Haisch, Green et al. 1997). However, longer WITs have resulted in satisfactory functional graft recovery in animal models for NHB kidney transplantation (Matsuno et al., 1999). This suggests that setting an absolute threshold for WIT is difficult. In clinical practice other parameters such as the age and general health of a prospective NHB donor and the temporal progression of organ ischemia during the dying process are relevant.

Not all transplant teams share the opinion that WIT is of primary importance, (Alonso et al., 1997). Alonso et al. argued that a still-to-be-defined allowable period of warm ischemia does not alter outcomes in NHB renal grafting. While they reported significantly increased rates of delayed graft function in their NHB donor kidneys, 3 month recovery rates were no different with WIT >2 hours. It would seem inherently logical that the duration of warm ischemia might be directly related to long-term transplant viability, but no evidence for this supposition could be identified during this review.

Among organs that may be transplanted, the lung is unique in its ability to withstand warm ischemia. Because of its histologic structure, consisting primarily of elastic tissue, the lung has minimal metabolic requirements. Furthermore, the alveolocapillary membrane of the lung can meet its requirements for oxygen through direct diffusion. Potential controlled NHB lung donors would be intubated and typically ventilated with oxygen, thereby maintaining the saturation of intra-pulmonary blood. Furthermore, the pulmonary endothelium is also capable of functioning for several hours following circulatory arrest. For reasons not described in the reviewed literature, this continued functioning prevents clot formation following cardiac death. Although systemic heparin was administered to the donor patient described in the report by Steen, many centres performing NHB lung transplantation no longer routinely administer heparin to the NHB lung donor (Steen et al., 2001). In addition to traditional eligibility requirements for NHB organ donation, Steen et al.'s only other mandatory requirement was that cooling should be initiated within 60 minutes of witnessed arrest or failed resuscitation.

## International NHBD Protocol Survey

Warm Ischemia Time Limits – Controlled DCD		
Site	Definition	Limits
<b>IOM Recommendations</b>		
IOM	Per OPO guidelines. Further research to establish effect of warm ischemic time on transplant outcomes is advised	
<b>NTL Protocols</b>		
NTL	Cardiocirculatory standstill to start of cooling	150 min.
<b>UK Protocols</b>		
UK1	MAP is less than 50 mmHg to cold perfusion	Keep to an absolute minimum
UK2	NA*	NA*
UK3	SBP $\leq$ 55 mmHg to cold perfusion (for kidney and liver ) Asystole to cold flush (lungs)	Kidney $\leq$ 40 min. liver $\leq$ 20 min. lungs < 90 min. (< 60 min. ideal)
UK4	NA*	NA*
<b>U.S. Protocols</b>		
No information contained in any of the U.S. protocols		

NA\*: no information provided in document

Warm Ischemic Time Limits – Uncontrolled DCD		
Site	Definition	Limits
UK	SBP $\leq$ 55 mmHg to cold perfusion (for kidney and liver) Asystole to cold flush (lungs)	kidney $\leq$ 40 min. liver $\leq$ 20 min. lungs < 90 min. (< 60 min. ideal)
NTL	Initial cardiac arrest to start of cooling	150 min. (provided cardiac arrest to adequate resuscitation $\leq$ 30 min.)
SP	Cardiac arrest to bypass	<120 min. (provided cardiac arrest to CPR < 15 min.) (Note: also requires < 120 min. of hemodynamic instability/anuria prior to cardiac arrest)
IOM	Per OPO guidelines. Further research to establish effect of warm ischemic time on transplant outcomes is advised.	

## References

- Alonso A, Buitron J, et al. (1997). Short- and long-term results with kidneys from non-heart-beating donors. *Transplant Proc* 29: 1378-80.
- Haisch C, Green E, et al. (1997). Predictors of graft outcome in warm ischemically damaged organs. *Transplant Proc* 29: 3424-5.
- Light J, Kowalski A et al. (1996). New profile of cadaveric donors: what are the kidney donor limits? *Transplant Proc* 28: 17-20.
- Matsuno N, Kozaki K, et al. (1999). Importance of machine perfusion flow in kidney preservation. *Transplant Proc* 31: 2004-5.
- Steen S, Sjoberg T, et al. (2001). Transplantation of lungs from a non-heart-beating donor. *Lancet* 357(9259): 825-9.

## 8. Preservation Techniques: Controlled and Uncontrolled DCD

### Cold Storage versus Machine Pulsatile Perfusion

There are two primary means by which the kidney may be preserved following explantation: cold static storage and machine pulsatile perfusion (MPP). MPP was developed prior to the 1970s and became prevalent thereafter. This technique suffers from several disadvantages including the cost of the device and consumables, the risk of machine failure and the requirements for an operating technician. MPP was subsequently largely abandoned when the literature could find no evidence that long-term outcome was improved with MPP vs. cold storage alone (Opelz & Terasaki, 1982).

Following a period of enthusiasm for cold storage alone, attention shifted back to the use of MPP in the belief that rates of DGF might be diminished following MPP. There was evidence to suggest that DGF contributed substantially to the cost of post-transplant care with increased requirements for dialysis and longer hospital stays. Later reports suggested that DGF might also contribute to poorer long-term outcomes (Cecka & Terasaki, 1995). All of these factors contributed to a renewed interest in MPP. Wight et al. undertook a meta-analysis to determine the effectiveness of MPP relative to cold storage. Although they found that the literature was lacking in high quality studies, they concluded that MPP results in a 20% reduction in DGF in both NHB and heart-beating kidney donation with diminished cost requirements for the care of the transplant recipient when compared to costs of patient care when cold storage was utilized (Wight et al., 2003).

In donors after brain death, a retrospective United Network for Organ Sharing analysis of 60,827 cadaveric kidneys transplanted in the U.S. between 1988 and 1995 showed that the MPP exhibited a highly significant impact on the need for first-week dialysis and the benefit was increased in high-risk groups (age > 55 years, cold ischemic time > 24 hours).

The benefit of MPP may be related to:

1. The perfusate constantly delivers fresh solution to the allograft.
2. Measurement of renal resistive indices (Kootstra et al., 2002).
3. Measured metabolites such as glutathione S transferase in the perfusate which are correlated to more severe renal tubular injury (Daemen et al., 1997).

### References

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- Cecka J, Terasaki, P. (1995). The UNOS scientific renal transplant registry. United Network for Organ Sharing. *Clin Transpl* 5: 1-18.
- Daemen J, Oomen A et al. (1997). Glutathione S-transferase as predictor of functional outcome in transplantation of machine-preserved non-heart-beating donor kidneys. *Transplantation* 63(1): 89-93.
- Kootstra, G, Kievit J et al. (2002). Organ donors: heartbeating and non-heartbeating. *World J Surg* 26: 181-4.
- Opelz, G, Terasaki P. (1982). Advantage of cold storage over machine perfusion for preservation of cadaver kidneys. *Transplantation* 33(1): 64-8.
- Wight J, Chilcott J, Holmes M, Brewer N. (2003). The clinical and cost-effectiveness of pulsatile machine perfusion versus cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors. *Health Technology Assessment (Winchester, England)* 7(25):1-94.

## Appendix 3: Forum Agenda

### Thursday, February 17, 2005

- 14:00 Registration  
15:00 Reception  
15:30 **I: Forum Opening**  
**Welcome and Opening Remarks**
- Leah Hollins, Chair, CCDDT
  - Christopher Doig, MD, Forum Co-chair
- Forum Overview**
- Dorothy Strachan, Facilitator
- 16:20 **II: DCD – The Challenge in Context**  
Presentation/Discussion
- Sam D. Shemie, MD Forum Co-chair
- 17:00 Break  
17:20 **Perspectives on DCD**  
**Dialogue #1: Family**  
Presentations/Discussion
- Valerie McDonald
  - Susan McVey Dillon
- 17:55 **Dialogue #2: Health Care Professionals**  
Presentations/Discussion
- Ann Thompson, MD
  - Andrew Baker, MD
- 18:30 **Dialogue #3: Legal Considerations**  
Presentation/Discussion
- Kathy O'Brien, LLB
- 19:00 Dinner (MacKenzie Room)

### Friday, February 18, 2005

- 7:00 FRG Meeting  
7:30 Breakfast  
8:00 Agenda Overview  
8:10 **Perspectives on DCD (cont'd)**  
**Dialogue #4: Transplant and Critical Care**  
Presentations/Discussion
- Prof. Gauke Kootstra, MD (NTD)
  - Michael DeVita, MD

### Friday, February 18, 2005 (cont'd)

- 9:25 **III: Questions and Recommendations**  
**Death and Minimum Post-Mortem Criteria to Proceed with Organ Donation**  
Fundamental Principles, Donation Sequences
- Sam D. Shemie, MD
- 9:40 Break  
10:00 Group Work  
11:00 Plenary Summary  
11:20 Break  
11:40 **Withdrawal of Life Sustaining Therap to Death**  
Presentations/Discussion
- Graeme Rocker, MD
  - Anthony M. D'Allessandro, MD
- 12:25 Lunch  
Forum Recommendations Group (FRG) Meeting  
13:30 **Ethics of Interventions Related to Consent and Death**  
Presentations/Discussion
- James Dubois, PhD
  - George Agich, PhD
- 14:20 **Interval of Care from WLST to Death**  
15:15 Break  
16:00 Interval of Care (cont'd)  
17:15 Plenary Summary  
17:45 **Related Research: Policy, Practice and Knowledge Translation**  
Presentation/Discussion
- Bruce McManus, MD, PhD, Scientific Director, CIHR Institute of Circulatory and Respiratory Health
- 18:00 Closing  
Wine and Cheese Reception hosted by BC Transplant Society  
19:30 FRG Meeting

### Saturday, February 19, 2005

7:00	Management and Administration Group Meeting
7:30	Breakfast Buffet
8:00	Agenda Overview FRG Report Q and A
9:00	<b>American and European Transplant Perspectives</b> Presentations/Discussion <ul style="list-style-type: none"><li>• Anthony M. D'Allessandro, MD (USA)</li><li>• Richard Hasz (USA)</li><li>• Paolo Muiesan, MD (UK)</li><li>• J.R. Nunez, MD (Spain)</li></ul>
10:00	Break
10:20	<b>Panel/Discussion:</b> Above speakers and Prof. Gauke Kootstra, MD (NTD)
10:55	<b>Donor-Based Interventions</b> Group Work: Interventions Relative to Phases of Care in Controlled DCD
12:30	Lunch FRG Meeting
14:30	Plenary Summary
15:00	Group Work: Post-Mortem Interventions
16:15	Plenary Summary
16:30	<b>Death and Donation: Vicarious Trauma</b> Presentation/Discussion <ul style="list-style-type: none"><li>• David Kuhl, MD</li></ul>
17:05	Closing
19:00	Free evening for participants FRG Meeting

### Sunday, February 20, 2005

7:00	Breakfast Buffet
7:30	Agenda Overview
7:40	<b>IV: Reports</b> <b>Recommendations on Issues</b> Presentation/Discussion
9:00	Break
9:20	<b>Over-Arching Recommendations: Minimum Requirements for a DCD Program</b> Group Work
10:15	Break
10:30	Plenary Summary
11:00	<b>Management and Administrative Challenges</b> Presentation/Discussion <ul style="list-style-type: none"><li>• Janet Davidson</li><li>• Richard Hasz</li></ul>
11:20	<b>Related Research: Policy Practice and Knowledge Translation</b> Presentation/Discussion
11:35	<b>Post Forum Surveys: Overview and Feedback</b>
11:50	Concluding Remarks Forum Closing
12:00	Light Lunch
12:30	Steering and Planning Committee Debriefing FRG Meeting

This event was an Accredited Group Learning Activity (Section 1) as defined by the Maintenance of Certification program of the Royal College of Physicians and Surgeons of Canada. This program has been reviewed and approved by the office of Continuing Medical Education and Professional Development, University of Calgary. Participants may claim up to a maximum of 21.5 study credits.

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## Donation After Cardiocirculatory Death: A Canadian Forum

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## Donation After Cardiocirculatory Death: A Canadian Forum

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## Donation After Cardiocirculatory Death: A Canadian Forum

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