Report of a National Conference on Donation after Cardiac Death

April 7 - 8, 2005
• American Medical Association AMA
• Society of Critical Care Medicine SCCM
• American Association of Critical Care Nurses ACCN
• American Society of Anesthesiologists ASA
• Joint Commission on Accreditation of Hospital Organizations JCAHO
• American Society of Transplant Surgeons ASTS
• American Society of Transplantation AST
• Assoc. of Organ Procurement Organizations AOPO
• North Amer. Transplant Coord. Organization NATCO
• Scientific Registry of Transplant Recipients SRTR
• United Network for Organ Sharing UNOS

contractor of

Organ Procurement Transplant Network OPTN
• Division of Transplantation, HRSA DOT
• Center for Medicaid Services, HHS CMS
• National Association of Medical Examiners NAME
• National Kidney Foundation NKF
• World Health Organization WHO
• Eurotransplant
The Institute of Medicine (IOM), the SCCM, and the JCAHO have concluded that DCD is an ethically proper approach of recovering organs from a deceased patient for the purpose of transplantation.

The Canadian Council of Donation and Transplantation has recently convened a forum in Vancouver, British Columbia whose report promotes “patient-care based principles for providing the option of donation within a sound ethical framework” and supports donation after cardiocirculatory death.

Aim of this national conference to expand the practice of DCD in the continuum of quality end-of-life care.
When the withdrawal of life support has been consensually decided by the attending physician and patient, or by the attending physician and family member or surrogate (particularly in the hospital setting of the intensive care unit), a routine opportunity for DCD should now be available to all families for consideration and to honor deceased donor wishes.
Six working groups of conference participants to address specific DCD issues and fulfill objectives:

1) determining death by a cardiopulmonary criterion,
2) assessing medical criteria to predict DCD candidacy following the withdrawal of life support,
3) protocols for successful DCD organ recovery and subsequent transplantation,
4) initiating DCD in Donor Service Areas (DSA),
5) the allocation of DCD organs for transplantation,
6) the media, public perceptions, and DCD.
Determination of Death using the Cardiopulmonary Criterion

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Thomas P. Bleck, MD  University of Virginia

Stephen Ashwal, MD, Loma Linda University School of Medicine
Lisa Day, RN, PhD, UCSF School of Nursing
Michael Diringer, MD, Washington University
Richard Fine, MD, University Hospital of SUNY
Jeffrey Kahn, PhD, Fairview University Medical Center
Peggy Kosherzenko, Public Ledger Building
Chuck Mowll, JCAHO
Leslie Whetstine, ABD, PhD, Duquesne University
Linda Wright, University Health Network Toronto

Alexander Capron, LLB, World Health Organization
Mike DeVita, MD, University of Pittsburgh
James DuBois, PhD, DSc, Center for Health Care Ethics
John Haas, PhD, S.T.L, National Catholic Bioethics Center
Gauke Kootstra, MD, PhD, University Hospital Maastricht
Jerry Menikoff, JD, MD, Kansas University Medical Center
John Robertson, JD, University of Texas Law School
Mike Williams, MD, Johns Hopkins University
Ethical Axiom:

- to adhere to the dead donor rule:
  the retrieval of organs for transplantation should not cause the death of a donor
- Multiple organs should be removed only after death
  ("Donation after Cardiac Death").
The Criteria of Death:

Death of an organ donor may be determined by either circulatory or brain criteria, as defined in President’s Commission: *Defining Death*, 1981. In either of these clinical situations, a diagnosis of death requires that both cessation of functions and irreversibility be determined.
Irreversibility is recognized by persistent cessation of function during an appropriate period of observation.

The 2000 IOM report noted that “irreversible” cessation of cardiopulmonary function can be interpreted to mean several things:

1) will not resume spontaneously;
2) cannot be restarted with resuscitation measures;
3) will not be restarted on morally justifiable grounds.
Work Group Participants of this 2005 National Conference concluded that death occurs when cardiopulmonary function will not resume spontaneously.

In clinical situations where death is expected: once respiration and circulation cease (irrespective of electrical cardiac activity), the period of observation necessary to determine that circulation will not recur spontaneously (autoresuscitation) may be only a few minutes.
“Auto-Resuscitation”

- In analyzing data on auto-resuscitation, relevant event is cessation of circulation, it is not cessation of electrical activity.
- When life sustaining therapy is withdrawn, based on the limited data available, spontaneous circulation does not return after 2 minutes of cessation of circulation.
Testing Observation Duration

In 1997, the Institute of Medicine recommended “at least 5 minutes of observation”.

In 2001, the Society of Critical Care Medicine concluded “at least 2 minutes of observation is required, and more than 5 minutes is not recommended.” \((Crit\ Care\ Med\ 2001;29:1826-1830)\).
The IOM and SCCM recommendations were expert judgments.

The Work Group supported the wording of the SCCM that for DCD “at least 2 minutes of observation is required, and more than 5 minutes is not recommended”

Subsequent studies have not been conducted to provide a statistically valid basis for determining the minimum duration of observation that should occur to rule out the possibility of autoresuscitation of circulation.
Assessing Medical Criteria to Predict DCD Candidacy Following the Withdrawal of Life Support.

Stephen Heard, MD: U Mass Medical Center
Stanley Rosenbaum, MD: Yale University School of Medicine
Justine Medina, RN, MS: American Association of Critical-Care Nurses

Peter Abt, MD, Strong Memorial Hospital
Richard Brilli, MD, Cincinnati Children’s Hospital Medical Center
Constance Donovan, RN, St. John’s Emergency Trauma Center
Barry Friedman, RN, Children’s Medical Center of Dallas
Rick Hasz, MFS, Gift of Life Donor Program
Tracy Koogler, MD, Univ of Chicago
Joe Nespral, Texas Organ Sharing Alliance
Tim Pruett, MD, UVA Health Sciences Center
Sally Webb, MD, Medical University of South Carolina
Christine Zawistowski, LeBonheur Children’s Medical Center
Maggie Allee, RN, JD, Oregon Health Science Univ.
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Nancy Knudsen, MD, Duke University Medical Center
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Susan Palmer, MD, Oregon Anesthesiology Group
Gail Van Norman, MD, University of Washington
Ken Wood, DO, University of Wisconsin Hospital
Assessing Medical Criteria to Predict DCD Candidacy Following the Withdrawal of Life Support.

- The conditions to consider DCD:
  - irreversible brain injury,
  - end-stage musculoskeletal disease,
  - high spinal cord injury.

- Potential candidates for DCD include patients whose life sustaining treatment is under consideration for withdrawal, and who would likely die soon after the withdrawal/refusal of this treatment.
Medications and interventions not relevant to the withdrawal of treatment prior to the declaration of death in a DCD patient:

- After the decision to withdraw life sustaining therapy has been made (but before the process has begun) special transplant related medications may be administered or interventions may occur.

- Vasodilators, anticoagulants and anti-oxidants or the intervention of pre mortem vessel cannulation require specific informed consent that addresses:
  - the added potential risks of hastening death
  - the potential benefit of improving the opportunity for successful transplantation.
Criteria that Predict Cardiac Death after Withdrawal of Treatment:

- Evidence based clinical judgment should be used to assess whether cardiac death will likely occur within a time period allowing successful DCD.

University of Wisconsin has developed an algorithm: score is computed which is based upon the patient's age, BMI, O2 saturation, method of intubation (endotracheal versus tracheostomy), level of spontaneous respiration, and the requirement for vasopressors, all of which indicate likelihood of death within one hour after extubation.
Protocols of DCD organ recovery and successful transplantation

Tony D’Alessandro, MD: University of Wisconsin Hospital
Bob Gaston, MD: University of Alabama at Birmingham
Michael Abecassis, MD, Northwestern Memorial Hospital
Viken Douzdjian, MD, Legacy Transplant Services
Sandy Feng, MD, PhD, UCSF Medical Center
Mitch Henry, MD, Ohio State University Hospital
Lynt Johnson, Georgetown University Medical Center
Cosme Manzarbeitia, MD, Albert Einstein Medical Center
Bob Merion, MD, University of Michigan Medical Center
Stephen Rayhill, MD, Oregon Health Sciences University
Harvey Solomon, MD, St. Louis University Hospital
Lewis Teperman, MD, NYU School of Medicine
Hasan Yersiz, UCLA Medical Center
Jeff Crippin, MD, Washington University
James Eason, MD, Ochsner Transplant Center
Rich Freeman, MD, New England Medical Center
Martin Jendrisak, MD, Barnes-Jewish Hospital
Alan Langnas, DO, Nebraska Medical Center
Lori Markham, RN, Midwest Transplant Network
Jeff Punch, MD, University of Michigan Medical Center
Kerri Robertson, MD, Duke University Medical Center
Patricia Talone, RSM, PhD, Catholic Health Association
Francis Wright, MD, Texas Transplant Institute
Adjusted* Graft Survival for DCD vs. non-DCD Kidney Transplants, 2000-2004

RR=1.05, p=0.48

*Adjusted for recipient age, sex, race, PRA, ESRD cause, years of ESRD, HLA mismatch, year of transplant, previous transplant, transfusions and donor age, sex, race, hypertension, diabetes, cause of death, creatinine, cold ischemia time.
Adjusted Liver Graft Survival
(1/1/2000 - 10/31/2003)

Adjusted HR = 1.85
P<0.0001

Un-Adjusted HR = 1.68
P<0.0001
Recipient Informed Consent:

- Workgroup participants considered the information that should be shared with a potential transplant recipient of a DCD organ to achieve informed consent.
- The process of informed consent should be done in phases, with a discussion of the current characteristics of the deceased donor pool at the outset of a listing of a patient (NY State Commission).
- This initial informed consent discussion should include the transplantation of organs from donors with varying degrees of risk of failure when compared to ideal donor.
Recipient Informed Consent:

- At the time of the proposed transplantation, final consent should be obtained as the physicians have a more precise assessment of the risks associated with undergoing a DCD (or ECD) transplant versus the risk of waiting for the next available donor (in the context of the waiting candidates’ severity of disease and mortality risk).
Initiating and Increasing DCD in Donation Service Areas (DSA)

Howard Nathan: Gift of Life Donor Program
Bill Marks: MD, PhD, Swedish Medical Center
Kevin O’Connor, New England Organ Bank

Charles Alexander, Transplant Resource Center of Maryland
Esther Marie Carmichael, CMS
Susan McVey Dillon, Donor Family Representative
Carlos Esquivel, MD, PhD, Stanford University Medical Center
Rob Kochik, New York Organ Donor Network
Barbara LeTourneau, MD, MBA, Regions Hospital
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David Powner, MD, University of Texas Houston Medical School
David Shaffer, MD, Vanderbilt University Medical Center
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Alison Smith, RN, BSN, Gift of Hope
Katherine Turrisi, MSN, Medical University of South Carolina Transplant Center

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Danielle Cornell, LifeQuest Organ Recovery Services
Lynn Driver, Indiana OPO
Gwen George, Gift of Life Donor Program
Dianne LaPointe Rudow, ANP, Columbia Presbyterian
Tom Mone, OneLegacy
Friedrich Port, MD, URREA
Jorge Reyes, MD, University of Washington Medical Center
Paul Schwab, MA, MPA, AOPO
Michael Shapiro, MD, Hackensack University Med. Center
25% of DSAs (15) accounted for 79% of all DCDs Recovered
### 20 OPOs Recovering > 5 DCD 2004

<table>
<thead>
<tr>
<th>OPO</th>
<th>Recovered</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gift of Life</td>
<td>47</td>
<td>12%</td>
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<tr>
<td>NEOB</td>
<td>38</td>
<td>19%</td>
</tr>
<tr>
<td>Gift of Hope</td>
<td>36</td>
<td>12%</td>
</tr>
<tr>
<td>Life Center NW</td>
<td>33</td>
<td>19%</td>
</tr>
<tr>
<td>Midwest</td>
<td>28</td>
<td>18%</td>
</tr>
<tr>
<td>UW</td>
<td>27</td>
<td>20%</td>
</tr>
<tr>
<td>Life quest</td>
<td>18</td>
<td>17%</td>
</tr>
<tr>
<td>Michigan</td>
<td>14</td>
<td>5%</td>
</tr>
<tr>
<td>CORE</td>
<td>14</td>
<td>9%</td>
</tr>
<tr>
<td>WRTC</td>
<td>12</td>
<td>10%</td>
</tr>
<tr>
<td>NYFL</td>
<td>11</td>
<td>21%</td>
</tr>
<tr>
<td>TRC MD</td>
<td>10</td>
<td>10%</td>
</tr>
<tr>
<td>Louisiana</td>
<td>8</td>
<td>5%</td>
</tr>
<tr>
<td>MTA</td>
<td>8</td>
<td>7%</td>
</tr>
<tr>
<td>One legacy</td>
<td>7</td>
<td>2%</td>
</tr>
<tr>
<td>Carolina</td>
<td>7</td>
<td>5%</td>
</tr>
<tr>
<td>Golden State</td>
<td>7</td>
<td>15%</td>
</tr>
<tr>
<td>NYODN</td>
<td>6</td>
<td>2%</td>
</tr>
<tr>
<td>NJTO</td>
<td>6</td>
<td>4%</td>
</tr>
<tr>
<td>Iowa</td>
<td>6</td>
<td>15%</td>
</tr>
</tbody>
</table>

Source: AOPO annual survey
Initiating and Increasing DCD
in Donation Service Areas

OPTN/UNOS

- Revise transplant center and OPO membership criteria to require DCD polices and protocol
- Establish organ specific sub-committees on DCD to address organ specific suitability criteria and allocation
- Conduct financial analysis of long term impact of DCD organ use on transplant centers
- Use regional meetings as venue for DCD discussion
Initiating and Increasing DCD in Donation Service Areas

- AOPO
  - Add DCD component to OPO accreditation standards

- JCAHO
  - Revise accreditation standards to require hospitals to implement DCD protocols
  - Treat lack of a DCD protocol as a requirement for improvement
Impact of DCD upon DBD:

A difference in how the increasing incidence of DCD in the U.S. is affecting the number of DBDs was compared to that of the Netherlands.

Unlike the Netherlands, which experienced a 21% decrease in DBDs (159 -> 126) during the most recent 5 year period in which there was a 129% increase in DCD (41 -> 94) the U.S. has increased its total DBD while at the same time accelerating DCD organ recovery.
United States Organ Procurement Organization Experience

**Donors / DCD**

**1995 – 2004**

<table>
<thead>
<tr>
<th>Year Donor Recovered</th>
<th>Number of Donors (includes DCDs)</th>
<th>Number of DCDs</th>
<th>DCD Percent of Total</th>
<th>Number of OPOs with at least one DCD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td>5,358</td>
<td>64</td>
<td>1.2%</td>
<td>22</td>
</tr>
<tr>
<td>1996</td>
<td>5,418</td>
<td>71</td>
<td>1.3%</td>
<td>21</td>
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<tr>
<td>1997</td>
<td>5,477</td>
<td>78</td>
<td>1.4%</td>
<td>19</td>
</tr>
<tr>
<td>1998</td>
<td>5,801</td>
<td>82</td>
<td>1.4%</td>
<td>16</td>
</tr>
<tr>
<td>1999</td>
<td>5,849</td>
<td>101</td>
<td>1.7%</td>
<td>18</td>
</tr>
<tr>
<td>2000</td>
<td>5,800</td>
<td>111</td>
<td>1.9%</td>
<td>22</td>
</tr>
<tr>
<td>2001</td>
<td>6,109</td>
<td>166</td>
<td>2.7%</td>
<td>29</td>
</tr>
<tr>
<td>2002</td>
<td>6,226</td>
<td>190</td>
<td>3.1%</td>
<td>31</td>
</tr>
<tr>
<td>2003</td>
<td>6,214</td>
<td>264</td>
<td>4.2%</td>
<td>32</td>
</tr>
<tr>
<td>2004</td>
<td>7,156</td>
<td>389</td>
<td>5.4%</td>
<td>41</td>
</tr>
</tbody>
</table>
Unprecedented Monthly Donor Records

Organ Donors

January 1999 to December 2005
Impact of DCD upon DBD:

- 16 DSAs accounting for 80% of DCD donation in 2004 increased DCD, SCD, and ECD donor recovery from 2003 to 2004:
  - 49.3% increase for DCD
  - 9.4% increase for SCD
  - 3.8% increase for ECD
  - Donation rate increased from 50% to 53.9%

- In 2004, non-DCD recovery positively associated with DCD recovery among the 59 DSAs.
The message to be conveyed about DCD to the public and professional community is provided by the following:

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