CHILDREN'S HOSPITAL BOSTON

REPORT OF THE TASK FORCE ON DONATION AFTER CARDIAC DEATH

December 2006

This report was prepared by Charlotte Harrison and Dr. Peter Laussen, Co-Chairs of the Task Force on Donation after Cardiac Death at Children's Hospital Boston. The information contained herein has been presented to and discussed in detail by the Task Force. The content of the report has been reviewed and approved by the Task Force members as an accurate reflection of their deliberations.

Acknowledgments

The Task Force acknowledges with appreciation the support received from the President and CEO of Children's Hospital Boston, Dr. James Mandell, the Senior Vice President for Patient Care Operations, Eileen Sporing, and the Chairpersons of the Ethics Advisory Committee: Christine Mitchell, Director of the Office of Ethics, and Dr. Jeffrey Burns, Chief of the Division of Critical Care. In addition, we thank the individuals listed below for their contributions to this project.

New England Organ Bank
Kevin O'Connor, Executive Director

Children's Hospital Boston
Dorothy Beke, RN, CICU Nursing
Jeffrey Burns, MD, Chief, Division of Critical Care
Amy Durall, MD, MSICU Fellow
Michelle Hogle, Research Assistant
Heung-Bae Kim, MD, Transplant Surgery
Elaine Meyer, RN, MSICU
Christine Mitchell, RN, Office of Ethics
Lisa Pixley, RN, MSICU Nursing
David Urion, MD, Neurology

Administrative Support
Jane Bennett, Office of Ethics
Lynne Patkin, Cardiac ICU

TASK FORCE MEMBERS

Comeau, Meg, MHA	Parent Resource Center (Phase I) Director, Catalyst Center (Phase II)
Craig, Nancy, RRT	Respiratory Care
Coulter, David, MD	Neurology
Curley, Martha, RN, PhD, PAAN	Critical Care
Harmon, William, MD	Nephrology
Harrison, Charlotte, JD, MPH, MTS, Co-Chair	Office of Ethics
Hoffman, Roberta, LICSW	Social Work
Kraft, Patti, JD	Public Member
Laussen, Peter, MBBS, Co-Chair	Cardiac ICU
Lillehei, Craig, MD	Surgery
Micheli, Anne Jenks, RN, MS (Phase I)	NES/Admin/OR
Berlandi, Jackie, RN, MS, CNOR (Phase II)	NES/Admin/OR
Randolph, Adrienne, MD, MSc	MSICU
Robinson, Mary, MA, M.Div	Pastoral Care/Chaplaincy
Taylor, Patrick, BA, JD	General Counsel
Truog, Robert, MD	Ethics/MSICU
Vesel, Tamara, MD	PACT Clinician
Waltz, David, MD	Pulmonary

TABLE OF CONTENTS

Children's Hospital Boston
President and Chief Executive Officer
Department of Urology

HARVARD MEDICAL SCHOOL
Professor of Surgery
The Robert and Dana Smith Professor

James Mandell, M.D.
Children's Hospital Boston
300 Longwood Avenue
Boston, Massachusetts 02115
phone 617-355-8555 | *fax* 617-730-0630
james.mandell@childrens.harvard.edu

CHILDREN'S HOSPITAL BOSTON
TASK FORCE ON DONATION AFTER CARDIAC DEATH

COMMITTEE CHARGE

President and Chief Executive Officer, James Mandell, and Senior Vice President for Patient Care Operations, Eileen Sporing, upon recommendation of the Medical Staff Executive Committee, and with support from the Office of Ethics, have appointed a multidisciplinary Task Force on Donation after Cardiac Death, with the following charge:

- To determine whether Children's Hospital Boston should adopt a protocol for organ donation after cardiac death (DCD) (Phase 1); and
- If that determination is affirmative, to develop a DCD protocol for use at the Hospital and recommend a process for implementation)(Phase 2).

The responsibilities of the Task Force shall include:

1. Consideration of current ethical and legal opinions and clinical questions about donation after cardiac death, particularly in pediatrics;
2. Gathering of empirical data concerning whether there should be a protocol at Children's Hospital providing for donation after cardiac death, including but not limited to the policies, practices and experiences of other hospitals and organ procurement organizations that have instituted or rejected DCD protocols for pediatric patients; any financial or other practical ramifications of the adoption of a DCD protocol at Children's; and the current attitudes and values of the Children's community related to donation after cardiac death;
3. Determination of the appropriateness of a pediatric DCD protocol at Children's Hospital Boston in light of the values and mission of the Hospital;
4. Presentation of an initial report to MSEC by summer 2005;
5. If such a protocol is deemed appropriate for the Hospital, the Task Force shall also:
   (a) Develop a DCD protocol for use at the Hospital, including safeguards addressing ethical concerns;
   (b) Recommend a process for implementation of the protocol, including measures to increase the knowledge and sensitivity of the Hospital community and the public to the clinical, ethical and legal issues raised by DCD.

January 11, 2005

EXECUTIVE SUMMARY

Report of the Task Force on Donation After Cardiac Death
Children's Hospital Boston

December 2006

1. SUMMARY OF TASK FORCE ACTIVITIES

1.1 PHASE I DELIBERATIONS

Work Plan

1. Review of published literature and other data, including:
   A. Institute of Medicine reports (1997, 2000)
   B. Organ Donation: numbers and outcomes with particular reference to DCD
   C. Pediatric Transplantation: current state and role for DCD
   D. The Process of DCD, including procedures and timeline

2. Review of legal and ethical issues

3. Research by Task Force subcommittees on:
   A. Number of possible candidates for DCD at CHB
   B. Values and attitudes towards DCD among staff at CHB
   C. Values and attitudes toward DCD among families and the public
   D. Policies toward DCD, including protocols and experience, from 17 pediatric institutions
   E. Religious issues pertinent to DCD
   F. Financial implications for the institution and families

Recommendation to the Medical Staff Executive Committee: Phase I

In July 2005, a summary of the Phase I deliberations from the Task Force on DCD was presented to the Medical Staff Executive Committee. This report stated that a protocol for DCD could be consistent with the mission of Children's Hospital provided eight foundational conditions were met. These eight foundations were:

1. Each child will be an appropriate candidate for withdrawal of life support under circumstances not involving the prospect of organ donation.

2. The withdrawal of life support process will be consistent with established practices at CHB, and there will be no physical harm, suffering or hastening of death to the child by the DCD process / protocol. The withdrawal of life support will be conducted in a compassionate and sensitive fashion that respects and preserves the human dignity of the patient.

3. There will be rigorous oversight of protocol development and the subsequent implementation. Resources will be made available to ensure independent oversight and monitoring of the DCD process and outcomes, with controls and authority established to prevent conflicts of interest, variance from the established protocol, and violations of any of these eight foundational criteria.

4. CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but the implementation of the protocol will not alter the quality of care in the ICU or the trust of

families that the welfare of their child is their and the staff's paramount concern. DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.

5. Participating families will give genuine informed consent that includes a statement that parents can change their mind at any time in the process. They will be informed of (i) the differences between the orchestration and experience of death, for both their child and themselves, if their child is going to be a DCD donor or not, and (ii) other facts likely to make a difference in their decision (*e.g.*, the likelihood of the organs going to another child).

6. The child will clearly be dead, which implies no potential for cognition before organ removal takes place, and our criteria for declaring death, including our concept of "irreversibility," will be ethically and medically justifiable.

7. Diversity in religious, cultural and personal values will be respected. Staff who object to DCD may avoid participation.

8. There will be no extra financial costs to the family from DCD participation.

Motion presented to the Medical Staff Executive Committee:

"That MSEC approve the Phase I Report & Recommendation of the Task Force on Donation after Cardiac Death, and support the protocol-development proposed by the Task Force for its second phase, with the understanding and intent that a DCD protocol should be adopted at CHB only if it meets the conditions established by the Task Force."

Passed unanimously by MSEC 7-12/2005

1.2 PHASE II DELIBERATIONS

Work Plan

1. A pediatric protocol was developed, debated, refined and eventually approved as being appropriate for implementation at CHB if DCD were offered.

2. As part of the deliberations during protocol development, separate subcommittees reviewed key questions regarding informed consent and time to death (the waiting period from the onset of acirculation to beginning organ procurement).

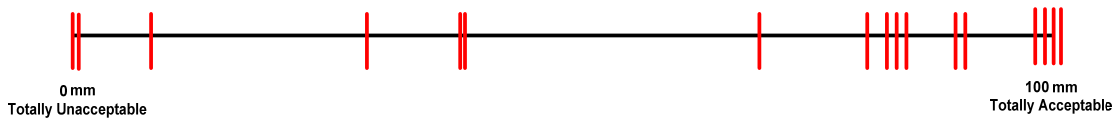
3. An additional subcommittee reviewed ethics literature and actual practice at CHB regarding expectations as to the best interest standard for decision-making on behalf of children (a standard that could not be met in DCD), met with Ethics Committee members and prepared a report suggesting a rationale whereby DCD could be an ethical choice by parents if certain strict protocol safeguards were met.

Status of Consensus

There was general agreement that the protocol designed by the Task Force is the best we could develop for pediatric DCD at CHB. However, consensus was not reached at the end of Phase II deliberations as to whether the protocol should be implemented. A minority of members concluded that some of the 8 foundational conditions for DCD, established by consensus in Phase I, could not be met.

At the completion of Phase II deliberations in March 2006, all Task Force members were asked to indicate on a scaled line (0-100 mm) their position as to whether the DCD protocol met the mission of CHB and the eight foundations defined at the end of Phase I deliberations.

The question: ***"Offering DCD on the terms of the protocol is acceptable to the mission of Children's Hospital".*** The spectrum of opinions is demonstrated on the line below.



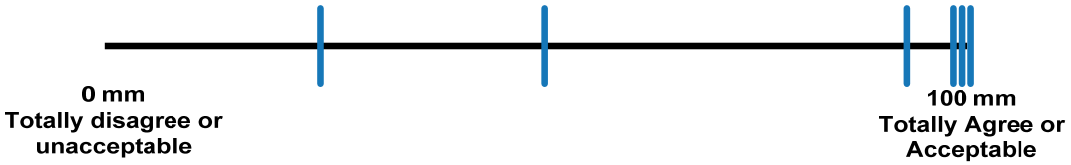
After Phase II, the co-chairs worked off line with those Task Force members who were skeptical of DCD in effort to determine if there were circumstances in which they would consider DCD. The co-chairs wrote the DCD report, including a section on the Pros and Cons of DCD. This section was distributed to Task Force members and the Task Force reconvened 9/27/06 for a final vote. Aspects of DCD were discussed and clarified and the members asked to vote on 5 statements, which fundamentally addressed the questions:

- Should DCD only be offered for adults and mature or emancipated minors who are included on a donor registry?
- Should DCD be offered for all patients, irrespective of age?
- Should implementation be delayed until further data or research is available?

STATEMENT 1:

Considering only the welfare and rights of DCD candidates and their families, DCD can be an acceptable choice for families if conducted under the proposed protocol.

Only for competent adults and mature or emancipated minors who have signed donor cards or entered their names in a donor registry.



NB: 11 Task Force members affirmed DCD for all possible candidates and not only those on a donor registry; therefore, they completed statements 2 and 4 but not statements 1 and 3.

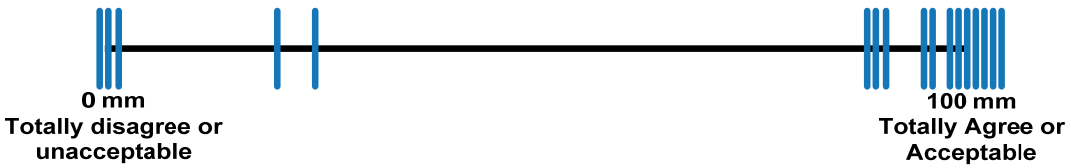
Please indicate if any of the 8 foundations have not been met with respect to this question.

- Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.
- Respect for patient autonomy. In keeping with current practice around family-centered care, patient-centered care. Foundation #7 as relates to families and patients. I agree this excludes other pediatric patients.
- Abstain—I certainly support it in these donors, but I would not limit it to this age category.
- As a pediatric institution CHB must take a leadership position in pediatric DCD.

STATEMENT 2:

Considering only the welfare and rights of DCD candidates and their families, DCD can be an acceptable choice for families if conducted under the proposed protocol.

For all possible candidates, including small children



Please indicate if any of the 8 foundations have not been met with respect to this question.

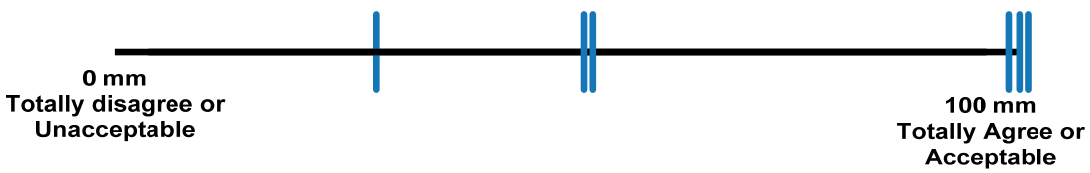
- Violates best interest standard
- Comfort level-challenging decision. Many factors to weigh.

- I believe that we give parents a lot of latitude to make major decisions about treatment options etc. even when children cannot give their consent/assent. So… if that's the felling who we believe has the best interest of the child in heart should be able to make decision about the DCD as well after the end of life of their child.
- I think that protocol is very thoughtful and well designed. It is crucial that this modality be available for families who desire it.
- The work, dedication, research, document etc. have resulted in a thorough presentation and summary of DCD regarding a pediatric health care facility. CHB is a leader in pediatric care and I hope that we will continue to be a leader in DCD, grow with it, change as DCD grows and be proactive in this field.
- I feel that parents can make this decision for minors. The decision to withdraw care is more weighty than DCD.
- I trust the clinical team will do the correct thing for the patients.
- Fails best interest standard and Kantian imperative.
- Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.
- DCD has risks, but it isn't so clearly harmful that no parent could justifiably choose it in the right circumstances. If we're only thinking of the one or two families a year who would choose it, we should respect their values and leave the choice with them, assuming all our protocol safeguards are in place.
- These children just are not dead yet. Their lives were cut short but they have the right to die in peace in their parent's arms in a safe place with nobody waiting behind the curtains to snatch their body away. These innocents should not be seen in pieces as possible kidneys or livers by those who profit from taking parts of their bodies. In life, young children are not altruistic so why would we assume they would be when near death?
- If offered – offer to all.

STATEMENT 3:

Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD protocol

Only for competent adults and mature or emancipated minors who have signed donor cards or entered their names in a donor registry



NB: 11 Task Force members affirmed DCD for all possible candidates and not only those on a donor registry; therefore they only completed statements 2 and 4 but not statements 1 and 3.

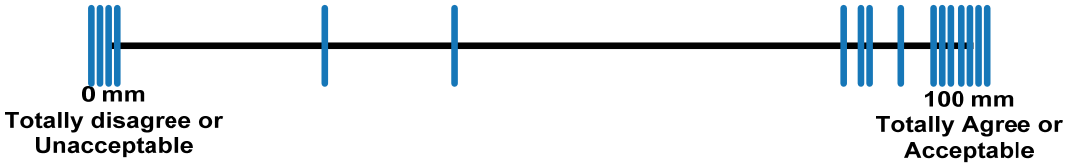
Please indicate if any of the 8 foundations have not been met with respect to this question.

- "A" DCD protocol to advocate for the wishes of these patients is important and desirable. We should support the autonomy of our adult and mature patients. Our policy might be to refer competent adults and mature minors to adult hospitals that do DCD more often and have the expertise. *e.g.* obstetrics. I do not see DCD at CHB as consistent with our/a pediatric mission.
- Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.
- This policy – compared to offering DCD for all ages -- reduces the effects of DCD on overall ICU care, since we would only have to consider DCD (*i.e.*, screen patient, involve organ bank, work in the shadow of conflicts of interest around end of life decisions) for this small and clearly defined sub-population. Other patients and families wouldn't be affected.
- Our mission is patient and family → the population is only part of our mission. Need to speak for the infant and child!
- Abstain-I certainly support it in these donors but I would <u>not</u> limit it to this age category.
- Please see statements—same reasons.

<u>STATEMENT 4</u>:

Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD protocol

For all possible candidates, including small children and infants



Please indicate if any of the 8 foundations have not been met with respect to this question.

- Violates best interest standard
- Given this DCD has emerged as appropriate option for organ donation it is imperative that Children's Hospital guide process with an appropriate model. My 95% only reflects that, as with any new venture, there are always concerns.
- After the work, I encourage CHB to be a leader locally and nationally. But let's do what we think is right—not news and what others hope to hear.
- I feel that parents can make this decision for minors. The decision to <u>withdraw care</u> is more weighty than DCD.

- Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD proposal.
- Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.
- Acceptability depends largely on (1) whether the protocol can be followed as intended, especially under pressure from the OPO, (2) whether the mandatory DCD screening of all candidates for withdrawal of life support will adversely affect the child-protective ethos of our ICUs, and (3) whether there is truly enough potential benefit to justify the ethical quandaries (including the possibility of premature withdrawal of life support) resulting from conflicts of interest. The donor children can't benefit and they're our first priority. Even the benefit to families is not convincing, as there is no research (mainly anecdotes selected by the OPO) and regrets seem likely. Much of the support for DCD seems driven by outside pressures rather than by our usual standards of care. (Foundations 1 & 4 aren't met.)
- For some families this will clearly be a good thing to offer and provide. For many families, the involvement of NEOB and the inherent conflicts of interest created by any DCD protocol will diminish the quality of the end-of-life care we provide. No changes in the protocol can entirely mitigate this inherent problem. Adrienne's data suggest that the number of organs procured in this way will be small. From the perspective of NEOB, the primary benefit of our adopting a DCD protocol will not be the organs obtained, but the public relations benefit of having our prestigious pediatric hospital "on board." For me, the cost / benefit analysis of this tilts in the direction of not adopting the protocol. I do recognize, however, that this will deny an important opportunity for a small number of families for whom this would be desirable

STATEMENT 5:

"Recognizing the special concerns applicable to pediatric DCD, CHB should defer implementation of the DCD protocol until adequate research is available to assess the effects of pediatric DCD on the quality of end-of-life care for children and families, including the decision-making process for withdrawal of life sustaining treatment. In the interim, CHB should work with other pediatric institutions and transplant centers to further such research."

Comments from Task Force members regarding the above statement:

- I feel like CHB should be the leader in this regard.
- CHB should take the lead in knowledge development in this area. We cannot wait for others to confirm our practice. We must confirm our own practice.
- We cannot do this type of research if we don't do this procedure. We can't let others to do the research for us.
- Hard to measure because I would not want CHB to wait but would hope CHB would be leader and share. I would want us to share and work with other pediatric institutions if asked but hope CHB would not wait for others if SLC with recommendation from DCD task force decides to go forward. CHB provides care that I believe is always aimed to be in the best interest of the

child/patient and believe we will continue this practice—not changing for DCD. The foundations required for DCD I believe (hope?) would be implemented. Thank you for all the great work and inviting me to participate.

- I do not think this is appropriate justification for not moving forward with DCD. On the other hand, I would favor ongoing scrutiny and refinement. Furthermore, if our deliberations have highlighted gaps in end of life care, these should certainly be addressed in an appropriate forum.
- I do not believe we need to defer implementation of DCD protocol, but we should participate in ongoing research as we move forward.
- We have an obligation to provide leadership—we are being looked at by other organizations. We have the resources and the responsibility. Regardless of final decision, we need to be out in front, providing background re: this thoughtful process.
- Applaud more research. We should continue to be lively participants in this topic. More research will not necessarily make it ethically more acceptable.
- We need to study the validity of the decision to WLS itself as well as the context (free of coercion) in which the decision to pursue DCD is made.
- Whatever our policy, we should be able to defend it openly to the public, or we risk losing their trust in the hospital and in transplantation. We should support a meaningful evaluation of the effects of DCD, and make a decision on that basis.
- Am not sure that more "research" or work with other institutions at this time will move process as believe we have put maximum effort into examining in exquisite detail. The complex issues for patients, families and staff though; believe we should work with other institutions as we and they progress to address all the salient and sticky issues, and for sure, try to refine protocols for procedures, decision making, support to patients, families and staff.

2. ISSUES REVIEWED AND DEBATED BY THE TASK FORCE

1. **General controversies regarding DCD**
   a. Conflicts of interest: tension between goals of patient care vs. organ preservation while donor is still alive
   b. Independence of decisions to (i) withdraw life support and (ii) donate organs
   c. Premortem procedures aimed at organ preservation
   d. Determination and certainty of death prior to procurement

2. **Special considerations in pediatric DCD**
   a. Greater uncertainty regarding neurological recovery or prognosis following severe brain injury in children, leading to greater risks of premature decisions to withdraw life support.
   b. Special sensitivity to children's extreme vulnerability and parents' grief.
   c. Greater difficulty meeting requirements for proxy consent to patient care changes
      i. DCD cannot be in the "best interests of the child"
      ii. Younger children can provide no basis for a "substituted judgment" that they would have consented to DCD (both donation & premortem treatment)
   d. Conflict between child-centered and family-centered care

3. **Environment at Children's Hospital Boston**
   a. Relationship between New England Organ Bank and ICU clinicians.
   b. Effects of DCD on integrity of end of life decision-making and care for most patients (not just DCD candidates) who die in our ICUs
   c. Consensus that no staff should be pressured or required to participate over moral or religious objections (DCD is morally controversial, not standard of care, and not a predictable job requirement).
   d. Uncertainty regarding community support.

4. **Other contentious issues for CHB Task Force**
   a. Significance of the low number of likely DCD candidates at CHB
   b. Conflict and possible conflict of interest within the Task Force

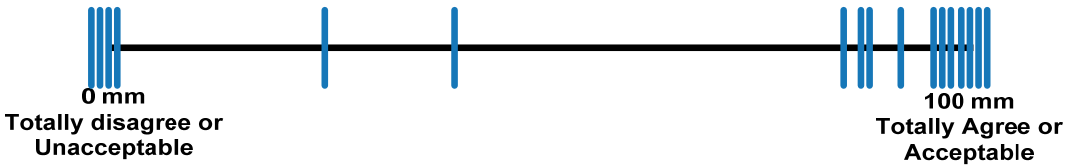
5. **Legal and regulatory requirements**
   a. OPTN proposal that all transplant hospitals must develop and implement DCD protocols by 1/1/07 (public comment period ended 10/27/06; OPTN Board meets 12/13/06)
   b. Institute of Medicine (May 2006) and JCAHO recommendations
   c. Massachusetts Donor Registry
   d. Clinicians' duty of care to patients, uncompromised by conflicts of interest; duty to avoid harms to patients from procedures solely to promote organ donation.

3. RECOMMENDATIONS

1. APPROPRIATENESS OF DCD FOR CERTAIN PATIENT POPULATIONS

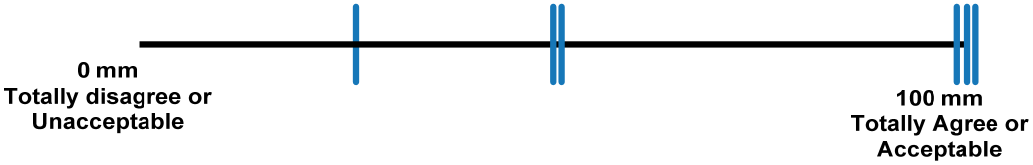
A. The Task Force did not reach consensus that the protocol should be offered to all medically-eligible patients and families, including young children. Polarized vote, with support of 11 members (including 4 involved in transplantation) and opposition from 6 members (including 3 who would have to participate in premortem DCD care).

"For all possible candidates, including small children and infants"



B. Almost consensus from the Task Force that DCD should be offered to adults and mature or emancipated minors who have chosen to enter a donor registry (14 of 17).

"Only for competent adults and mature or emancipated minors who have signed donor cards or entered their names in a donor registry"



NB: 11 Task Force members affirmed DCD for all possible candidates and not only those on a donor registry; therefore they only completed statements 2 and 4 but not statements 1 and 3.

C. All affirmative votes on both questions were contingent on the Hospital's adoption of the Protocol, Implementation Guidelines and Informed Consent Guidelines developed by the Task Force, as well as commitment to the following prerequisites:

2. PREREQUISITES FOR A FINAL DECISION TO OFFER DCD

There was consensus that no decision to offer DCD should be made until these steps had been undertaken.

A. ***Staff survey.*** Conduct an independent staff survey to see whether there is sufficient willingness to participate in DCD among staff in the units affected (ICUs, clergy) for

implementation to be feasible without coercion of staff or unacceptable disruption in continuity of patient care.

B. ***Community review.*** Establish a process for review by the community at large.

C. ***Improvements in OPO-ICU relationship***. The success of a DCD program is critically dependent on an atmosphere of collaboration and trust between CHB ICU clinicians and the NEOB. Given the persistent levels of discord, this will require involvement and direction from the most senior leadership at both CHB and the NEOB.

3. KEY IMPLEMENTATION GUIDELINES

Recommendations to ensure successful implementation include the following:

A. ***DCD service***: An independent DCD service and oversight structure should be established to minimize conflicts of interest, maintain integrity of the DCD process and protocol, and establish important new research in this field.

B. ***Staff education*** is necessary regarding organ donation in general and donation after cardiac death specifically. It is recommended staff also receive additional training to help address issues surrounding withdrawal of life support and introduction of organ donation to families, while attempting to minimize the conflict of interest involved in considering both decisions at once.

C. ***Review*****:** A thorough internal unit-specific debriefing should be undertaken after each DCD. An independent review of the protocol and implementation should be conducted after each of the first two cases, with the option of reconsidering whether DCD should continue to be offered.

4. NEXT STEPS

DCD WITHIN CHB

1. ***DCD should be offered at CHB for adults and mature or emancipated minors*** who have signed donor cards or are on a registry, if the units required to implement the protocol have sufficient staff who are morally comfortable with participating. Immediate steps toward this goal would include:

   A. Independent survey of ICU staff, clergy and others whose participation would be necessary.

   B. Review from larger community/public.

   C. Initiatives to improve ICU-OPO relationship.

   If outcomes of the above steps are positive, the Task Force recommends approval of the proposed protocol, establishment of an implementation committee, and identification of independent leadership to oversee DCD in the institution.

2. ***Whether (or when) to offer DCD for all patients*** or on a case-by-case basis is the difficult decision for CHB leadership. Task Force opinion was divided on this question, as detailed above. If senior leadership wishes to pursue this option, a staff survey in the affected units would provide important information for decision-making.

LEADERSHIP IN THE PROFESSION

1. ***Response to OPTN proposed by-law change.*** From a larger pediatric population perspective, DCD for children should perhaps not be viewed as an obligation or requirement, but rather optional until further information and research is available. CHB has the opportunity to take a leadership position in this regard. With executive approval, the Task Force co-chairs submitted a comment on the proposed OPTN Bylaw change recommending an exclusion of pediatric institutions from any mandate to implement DCD at present and initiation of research and a consensus conference on the effects of DCD on children and families. The comments were discussed by the Pediatric Subcommittee of OPTN. The Subcommittee has recommended a phased introduction for pediatric DCD, rather than the January 1, 2007 deadline. The Pediatric Subcommittee also supported the concept of consensus conference for pediatric DCD.

2. ***Dissemination of Task Force findings and protocol.*** In addition, the work started by the Task Force should be disseminated to the wider pediatric community and organizations such as NACHRI. It appears that no other pediatric institution has undertaken a project as extensive as this one, and other institutions have asked for information from us.

DETAILED REPORT

Task Force on Donation After Cardiac Death
Children's Hospital Boston

December 2006

SECTION I: BACKGROUND FOR DCD

SECTION II: PHASE I

SECTION III: PHASE II

SECTION IV: PROS AND CONS OF DCD

SECTION V: RECOMMENDATIONS

SECTION VI: APPENDIX

SECTION I

BACKGROUND FOR DCD

1. **INTRODUCTION**
2. **INSTITUTE OF MEDICINE REPORTS**
3. **ORGAN DONATION: NUMBERS AND OUTCOMES**
4. **THE DCD PROCESS**
5. **OBLIGATIONS TO ORGAN PROCUREMENT ORGANIZATIONS & REGULATORY BODIES**

SECTION I

BACKGROUND FOR DCD[a]

1. INTRODUCTION

The disparity between the number patients awaiting organ donation and the actual number of organs transplanted continues to be a significant health care issue. Over the past decade, the waiting list for organ recipients has continued to increase while the number of patients meeting brain death criteria and donating organs has remained relatively unchanged. Because the demand for organs continues to increase and patients die while on the waiting lists, there have been renewed efforts to increase the awareness and importance of organ donation through initiatives led by the Department of Human Health Services (DHSS) and Health Resource and Services Administration (HRSA), Institute of Medicine (IOM), UNOS and the Association of Organ Procurement Organizations, and regulatory agencies such as the Joint Commission on Health Care Accreditation. Over the past two years, the number of organ donations has started to trend upwards, with some of the success attributable to the national implementation of the Organ Donation Breakthrough Collaborative, sponsored by HRSA.

Determination of death by neurological criteria was incorporated into the Uniform Determination of Death Act (UDDA) in 1980[1], and since then organ procurement has predominantly been from heart-beating patients who fulfill brain death criteria. As an alternative strategy to increase the number of organs available for donation, over the past ten years there has been an increasing trend and recommendation for procurement of select organs from non-heart beating donors, also known as *"donation after cardiac death"* (DCD). The donation of organs after cessation of the beating heart is not a new concept and in the early history of transplantation, organs were obtained either from living donors or from patients declared dead after irreversible cessation of respiratory and cardiac function. The renewed interest in DCD is not only related to the potential to increase the procurement of organs for transplantation, but also comes from requests and interest expressed by families of patients with devastating and irreversible neurological injuries to pursue this form of donation when brain death criteria can not be met.

There are four categories for DCD donation, defined at the First International Workshop on Non-Heart Beating Donation (NHBD) held in Maastricht, The Netherlands, Table 1.[b] Category One donors are considered "dead on arrival"; Category Two donors have sustained cardiopulmonary arrest with an unsuccessful resuscitation attempt; Category Three donors are those who are "awaiting cardiac arrest"; and Category Four donors experience "cardiac arrest while brain dead".

[a] Section I of the Report was prepared by Peter Laussen.

[b] 1997 IoM report on Non-Heart Beating Organ Donation.

Table 1. A classification system for non-heart-beating organ donation

Category I:	Dead on arrival at the hospital
Category II:	Unsuccessful resuscitation ("uncontrolled DCD")
Category III:	Awaiting death by cardiopulmonary criteria ("controlled DCD")
Category IV:	Death by neurological criteria ("Brain death)

The Maastricht Category Three patients ("controlled" DCD) were defined as having irreversible brain injury but did not fulfill the criteria for brain death, and it is this group of patients whom we considered candidates for DCD.

Reference

1. Uniform Determination of Death Act, drafted by The National Conference of Commissioners on Uniform State Laws at its annual conference on July 26, 1980. Approved by the American Medical Association October 1980 and the American Bar Association February 10, 1981.

2. INSTITUTE OF MEDICINE REPORTS

1997

In 1997 the Institute of Medicine published a report regarding the medical and ethical issues in procurement of non-heart-beating organs[2]. This report made recommendations for national policy in seven specific areas, which included:

1. Development of written and locally approved non-heart beating donor protocols,
2. Public openness of non-heart beating donor protocols,
3. Case-by-case decision about the pre-mortem administration of medications,
4. Family consent for pre-mortem procedures if required,
5. Conflict of interest safeguards,
6. Determination of death in controlled non-heart beating donations by cessation of cardiopulmonary function for at least 5 minutes by electrocardiographic and arterial pressure monitoring, and
7. Family options be respected, including attendance at life support withdrawal and financial protection.

2000

Further to the 1997 report, the DHHS requested the IoM design a methodology to facilitate the adoption of DCD protocols by organ procurement organizations (OPOs). In 2000, an IoM workshop[3] recommended that:

1. All OPOs explore the option of non-heart beating organ transplantation either because of:
   A. Family requests,

   B. Health Care Financing Administration (HCFA) regulations that require all deaths or impending deaths be referred to the local OPO with the option of organ and/or tissue donation offered by a trained requestor,
   C. DCD has the potential to contribute substantially to the supply of organs and/or tissues for transplantation.
2. The decision to withdraw life sustaining treatment must be made independently of and prior to staff-initiated discussions of organ or tissue donation,
3. Statistically valid observational studies of patients after cessation of cardiopulmonary function need to be undertaken by experts,
4. Non-heart beating organ and tissue donation should focus on the patient and the family,
5. Efforts to develop voluntary consensus on non-heart beating donation practices and protocols should be continued,
6. Resources must be provided to sustain non-heart beating organ and tissue donations, and
7. Data collection and research should be undertaken to evaluate the impact of donation on family and providers, including attitudes and concerns, costs, and outcomes.

The guidelines and recommendations from the 1997 and 2000 IoM reports were thoroughly reviewed by the Task Force, and as contained in the section on *Pros and Cons of DCD*, were considered during our discussions and debates.

References

2. Non-Heart Beating Organ Transplantation: Medical and Ethical Issues in Procurement. Institute of Medicine, Division of Health Care Services. National Academy Press. Washington DC 1997, p.4

3. Non Heart Beating Organ Transplantation. Practice and Protocols. The Institute of Medicine. National Academy Press. Washington DC. 2000, pp. 3-5.

4. Organ Donation: Opportunities for Action. The Committee on Increasing Rates of Organ Donation. Institute of Medicine. National Academy Press. Washington DC. May 2006.

3. ORGAN DONATION

3.1 NUMBERS AND OUTCOMES

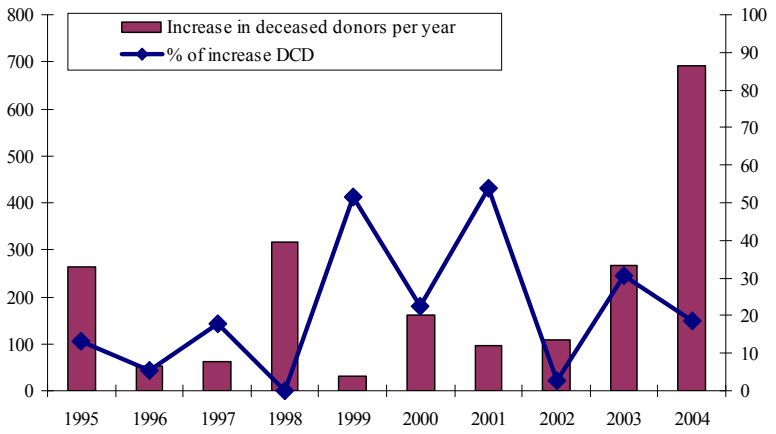
According to data provided by UNOS on their website and a recent IoM report[4], the number of organ donations from patients who fulfill cardiac death criteria has increased over the past decade, Table 2.

Table 2

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
Controlled DCD	11	46	49	60	48	64	100	151	154	236	366
Total Deceased Donors	5099	5362	5416	5478	5793	5824	5985	6080	6190	6457	7150
DCD %	**1.1**	**1.2**	**1.3**	**1.4**	**1.3**	**1.5**	**2**	**2.8**	**3.1**	**4.2**	**5.5**

In 2004, DCD donors accounted for 5.5% of all organ donors, although this of itself does not account for the overall increase in organ donations seen over recent years, Figure 1. Of the total increase in the number of deceased donors each year between 1994 through 2004, DCD donors comprised 17.9%.

Figure 1



In 2005 there were 14,489 patients who donated organs, 52% (7,593) were deceased donors, and there has been a steady increase in the total number of organs recovered (an average of approximately 1,100 more organs recovered each year than in the previous year). Nevertheless, the growth on the waiting list continues to be dramatic. While the donation of organs after cardiac death has certainly contributed to the overall increase in the number of organs transplanted, more so there has been an increase in organs procured from patients who fulfill brain death criteria. This a reflection of the success of new initiatives instituted by the UNOS such as the Organ Donation Breakthrough Collaborative.

The increase in the number of organs procured from donation after cardiac death protocols has primarily affected renal and liver transplantation[5]. Most of the DCD donors, according to UNOS data, are in the late teenage to mid adult ages, Figure 2, and the causes of death in these patients are primarily due to irreversible neurological injury from head trauma, anoxia, or cerebral vascular accident.

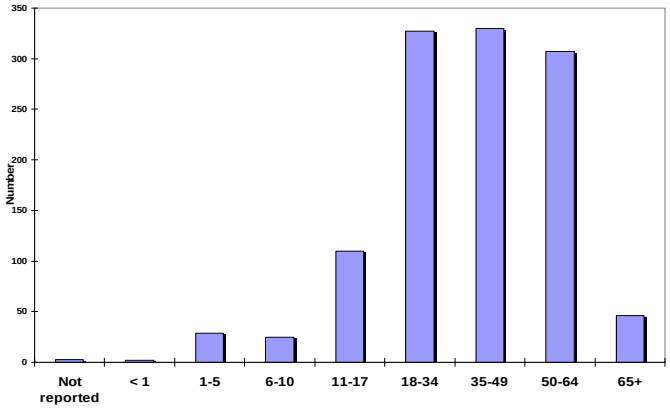


Figure 2. Age of DCD donors (UNOS 1994-2004)

The outcomes following DCD for kidney and liver transplantation have been reported by UNOS. For kidney transplantation, there is an increased risk for immediate post transplant delayed graft function when compared to organs transplanted from patients who meet brain death criteria (odds ratio 2.49, 95% CI 1.75-3.53 with a cold ischemic time < 13 hours)[5], however there is *not* an increased risk for early graft failure (OR 1.05, 95% CI 0.91-1.22) [5] nor a decrease in kidney 3-year graft or patient survival. For liver transplantation, however, there is an increased risk for early graft failure (odds ratio 1.85, 95% CI 1.51-2.26), but the three year graft and patient survival is no different when compared with livers transplanted from patients who met brain death criteria, Figure 3.

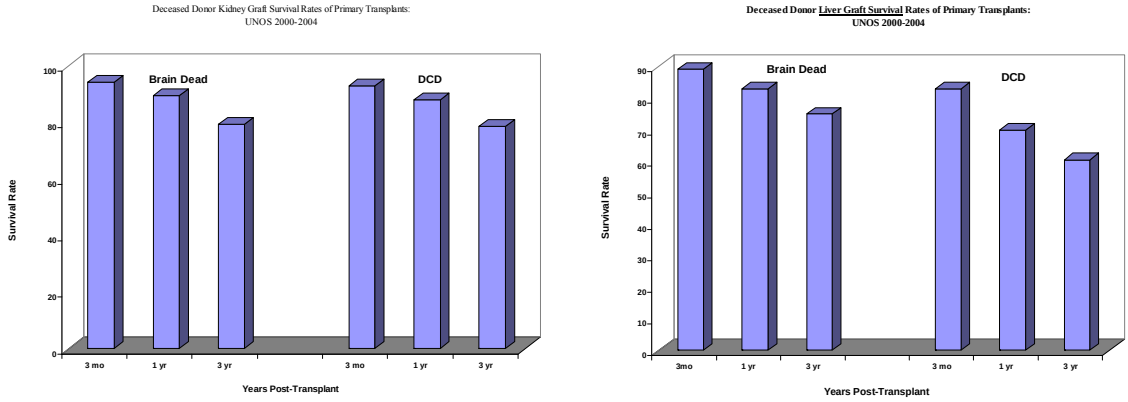


Figure 3: Brain dead versus DCD Kidney and liver graft survival

3.2 PEDIATRIC TRANSPLANTATION

Pediatric transplantation differs from adult transplantation in several important aspects, including the underlying cause of organ failure, co-morbid conditions, the complexity of surgical procedures, and the variable immune response and pharmacokinetic responses to immuno-suppressant drugs[6]. The North American Pediatric Renal Transplant Cooperative Study (NAPRTCS), the Studies of the Pediatric Liver Transplantation (SPLT) and the Pediatric Heart Transplant Study (PHTS) have been following patients after transplantation over the past decade. The number of children awaiting transplantation has increased by about 70% over the past ten years and children account for 3% of the patients on transplantation waiting lists. In 2003,

pediatric recipients represented 7% of all transplant recipients, but it is important to note that most organs procured from pediatric donors are more frequently transplanted into adult patients. Therefore there is no direct benefit to a specific pediatric institution to enhance their donation program because the number of organs procured will not necessarily benefit their specific pediatric population. In 2003, pediatric deceased donors represented 14% of all donors, and this number has been relatively stable over recent years, nevertheless, it is to the greater good that deceased pediatric donors remain part of the available transplant pool.

In 2005, 314 children under ten years of age received kidney transplants, as did 576 adolescents between 11-17 years of age. Young children have the best long term graft survival of any age group of transplant recipients, whereas in contrast, adolescents have a poorer longer-term graft survival which may be related to noncompliance with treatment regimens[6]. Hopefully, improved immunosupression protocols will reduce many of the side effects associated with drugs such as corticosteroids, and therefore improve longer term patient compliance. Pediatric concerns for liver transplantation focus on growth, which may also be inhibited after transplantation by the immunosupression regimens.

The pediatric experience of DCD is small compared to adults. A national survey in 1999 and 2000 of all organ procurement organization in the United Network for Organ Sharing (UNOS) showed that in 1999 29% (18 of 63) of all OPOs reported one active pediatric DCD protocol, and in 2000 56% of all OPOs reported at least one active protocol.[c] In 2000 there were a total of 40 active protocols for pediatric patients in the USA with all protocols explicitly requiring consent to donation only after the decision has been made to withdraw life sustaining treatment. It was noted in the survey that there was a wide variability among protocols with specific guidelines on non-therapeutic inventions intended to enhance organ viability and that there was inconsistency with the interval specified from cessation of circulation to declaration of death. More recent data from UNOS demonstrates an overall increase in the use of DCD for recovery of organs from pediatric patients, Figure 4. [d]

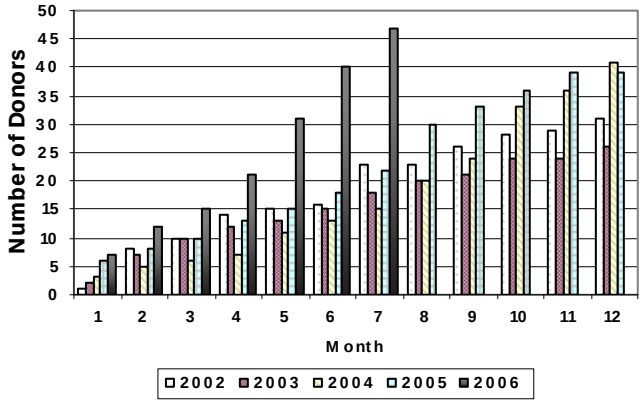


Figure 4. Cumulative experience with pediatric DCD reported to UNOS

[c] Dr Jeff Burns, Children's Hospital, Boston. Unpublished data

[d] Data provided by Dr. Heung-Bae Kim, Director, Pediatric Transplant Center, CHB

In 1998, the routine use of DCD was reported to have the potential of increasing organ donation at Children's Hospital of Philadelphia (CHOP) by up to 42%[7]. This data came from a retrospective analysis of over 6,000 admissions to a pediatric intensive care unit over a 4.5 year period, during which all deaths were identified and the potential DCD patients determined by the criteria of the decision to forgo life-sustaining therapy, death occurring within two hours of withdrawal of life support, and the absence of sepsis, HIV, hepatitis, or extracranial malignancy. To a significant extent, the impetus for that retrospective review was the independent request by two parents for organ donation when the decision to withdraw life support was reached.

A similar review was conducted at Children's Hospital Boston as part of the DCD evaluation[8], with somewhat different exclusion criteria and results. Focusing on possible DCD candidacy for renal transplantation, the charts of 254 deaths in our medical/surgical or cardiac intensive care units over a three year period from 2002-2004 were examined (see Appendix A). Assuming similar consent rates as for donation in patients diagnosed as being brain dead, it is estimated that there would be only approximately 2 patients each year in the ICUs and Children's Hospital who would likely be DCD donors.

References

5. Bernat JL, D'Alessandro Am, Port FK et al. Report of a National Conference on Donation after Cardiac death. Am J Transplantation 2006;6:281-291

6. Harmon WE, McDonald RA, Reyes JD, Bridges ND, Sweet SC, Sommers CM, Guidinger MK 2005. Pediatric transplantation, 1994-2003. *American Journal of Transplantation* 5(4):887-903.

7. Koogler T, Costarino AT Jr. The potential benefits of the pediatric nonheartbeating organ donor. Pediatrics 1998;101 (6):1049-52

8. Durall A, Laussen PC, Randolph A. Potential for Donation after Cardiac Death in a Children's Hospital. Pediatrics 2006; (in press)

4. THE DCD PROCESS

The withdrawal of life support during donation after cardiac death is very different from that of beating heart organ donation. There are competing concerns for assuring a dignified and compassionate withdrawal of life support, surrounded by parents and family, against the importance of limiting the warm ischemic time to organs and optimizing function prior to procurement and subsequent transplantation.

There are important steps during withdrawal of life support for DCD donation, and they are time limited, which places an additional strain on staff and resources. In many adult protocols, the withdraw of support usually occurs in the operating room, often with the patient draped and prepared for immediate laparotomy and organ procurement once death has been declared. This environment substantially limits the access for family and the process of withdrawing care is quite different than would occur in the critical care environment. Also, the process and logistics for withdrawal of care is foreign for operating room staff, and as such the environment and process by which withdrawal of life support takes place is substantially altered.

Depending on the OPO protocol, there can be pre-morbid procedures and drugs administered which offer no benefit to the patient, and could even cause harm or hasten death, and yet are deemed necessary for organ protection. This includes placement of new vascular catheters to facilitate exsanguination after death is declared, and administration of drugs, such as phentolomine and heparin, to possibly improve organ function after transplantation.

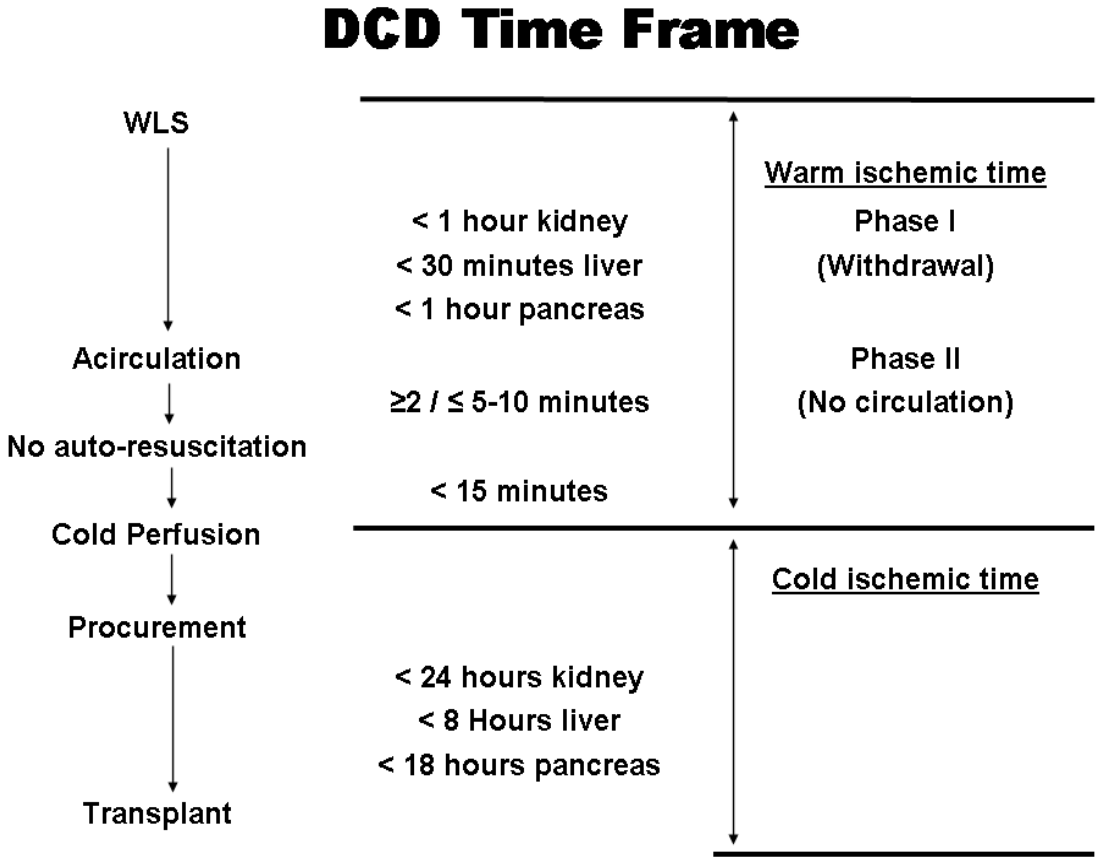
Once the patient has died, exsanguination and infusion of cold preservative solution to the body is necessary to provide donor organ protection prior to transplantation. The placement of a femoral artery and vein cannula prior to the withdrawal of support to facilitate exsanguination after death has been declared, can be associated with complications that may significantly affect the process of withdrawal and hasten death; this is generally no longer recommended by OPOs. If cannulation is therefore deferred until after death is declared in the operating room, laparotomy and placement of catheters in the aorta and inferior vena cava is required immediately after the period of waiting has determined that there is no auto-resuscitation[e] of the circulation. The immediacy and importance of this procedure after death severely limits the time families can spend with the body of their child, and in most circumstance, the family will need to be escorted from the operating room very soon after death has been declared. This is an emotionally charged time for families and staff, and the competing conflict between wanting to preserve the integrity and dignity of the withdrawal of life support process, against the need to preserve the function of the organ about to be donated, can be a significant source of concern.

The time frame and ischemic times recommended for DCD are shown in Figure 5. After withdrawal of support and extubation of the trachea, there is a period of warm ischemia as the

[e] Auto-resuscitation refers to the spontaneous and unassisted recovery of a heart beat and contraction of the heart muscle, no matter how ineffective, after death has been declared.

patient progresses to "acirculation"[f] and death is declared (Phase I). The time to acirculation is variable among patients, but is recommended that it occur within 60 minutes to prevent irreversible injury to donor organs. If patients have not reached acirculation within this time frame, they are no longer suitable candidates for DCD and are taken from the operating room and back to the intensive care unit to die. Once acirculation has occurred, there is a waiting period to make sure there is no auto-resuscitation of the circulation. This period of waiting during which there is no organ perfusion varies between DCD protocols, and is reported as short as 3 minutes and up to 10 minutes. After this waiting period, surgical incision is made and the period of cold ischemia (Phase II) begins with exsanguination and infusion of cold preservative solution.

Figure 5



[f] The term "acirculation" refers to a state of no blood flow throughout the body; the heart muscle does not contract, although there may be residual electrical activity, however abnormal, detected by ECG monitoring. This term is used to distinguish from "asystole" where there is no electrical (ECG) or mechanical (contraction) activity of the heart muscle.

5. OBLIGATION TO ORGAN PROCUREMENT ORGANIZATIONS AND REGULATORY BODIES.

The transplant organizations are committed to their mission, are well organized and have broad support. As a result, they have achieved important success promoting and developing initiatives at community, regulatory and government levels to increase organ donation. Primarily, organ transplantation initiatives have focused on adult donation, with the expectation that pediatric patients are included. This does not consider, however, the unique differences inherent in pediatric donation, and there is limited objective data regarding pediatric patients upon which to frame specific guidelines or protocols.

5.1 CENTER FOR MEDICARE & MEDICAID SERVICES REGULATION

In 1998, the Federal Department of Health and Human Services and Center for Medicare & Medicaid Services (CMS) changed the conditions for participation for hospitals receiving Medicare and/or Medicaid reimbursement with the introduction of regulation ***§482.45 "Condition of participation: organ tissue and eye procurement".*** The language used in this regulation is clear and definitive, although does not deal with specific pediatric concerns. For the patient who has died or whose death is imminent, the regulation provides autonomy and expectations for the OPO that could conflict with the primary responsibility of clinicians managing that patient. Salient excerpts include:

> *"The hospital must have and implement written protocols that incorporate an agreement with an OPO ... under which it must notify, in timely manner, the OPO or third party designated by the OPO of individuals whose death is imminent or who have died in the hospital."*

While ICU staff at CHB uniformly comply with notification of the NEOB after a patient has died or of a patient's imminent diagnosis of brain death, rarely do staff notify the NEOB of imminent death from withdrawal of life support in non-brain-death cases in which organ donation would necessarily rely on the implementation of a DCD protocol. The implementation of a DCD protocol therefore will reasonably require a change in practice by ICU attending staff, since the mandate described above will have become relevant to organ procurement in such cases.

> *"The OPO determines the medical suitability for organ donation…."*

This is an area of conflict for ICU staff who have cared for the patient and family, and for OPO requestors. In the DCD protocol developed by the Task Force, the NEOB agreed to specific contraindications to DCD and telephone screening that would assist with patient selection. This agreement should help to preserve the autonomy of medical decisions and quality of the discussions surrounding withdrawal of life support with the family.

> *"The Hospital must ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues or eyes, or decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor*

is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ and tissue donation" [g]

The definitive language used in this regulation has significant implications for ICU staff. There are no separate criteria for pediatric patients specified, nor an acknowledgment in the regulation that organ donation can be different for children than adults (we are unable to determine whether or not these considerations were discussed during the formulation of this regulation). Of note, this regulation does not expressly include DCD protocols, which is an important distinction; requesting organ donation from a patient who has already been declared dead is quite different from requesting organs from families who are struggling with the decision to withdraw life support from a patient who is not yet dead. The ICU staff at CHB, both on the Task Force and during the internal focus group, expressed concerns at being pressured by OPO requestors, and reported that their skills, ability and prior experience dealing with their patients' families had on occasions been ignored, or at least not appreciated or respected. More important perhaps, when trained requestors speak with families, their focus is understandably on increasing the "conversion rate", *i.e.,* the number of organs retrieved. As a result, concern was expressed within the Task Force that bias during discussions with families could assume a level that is in contrast to the standards now expected and enforced for informed consent prior to medical procedures or to enrollment in clinical research studies.

The NEOB prepared a Memorandum of Understanding based on the CMS interpretation of this regulation, and distributed it for signature by transplant programs in the New England region. In November 2006 the MOU was reviewed and discussed by Dr. Mandell, CEO, Drs. Jeffrey Burns and Peter Laussen from the M/SICU and CICU, Dr. Heung-Bae Kim, Director of the Pediatric Transplant Center, Kevin O'Connor, Executive Director of NEOB, and senior counsel at CHB including Stuart Novick and Patrick Taylor. It was agreed the MOU would be signed and Children's Hospital reaffirm its commitment to organ transplantation programs. The unique difference for pediatric patients and institutions was emphasized in a letter accompanying the MOU along with the need to establish policies and guidelines for collaborative practices between CHB and the NEOB.[h]

5.2 ADDITIONAL REGULATORY AND LEGAL CHANGES

During the 18 months of research, discussion and debate by the Task Force, significant changes and new initiatives occurred within the transplant community and in the oversight of organ donation that should also be considered by CHB leadership when considering a program for DCD. Specifically these have included:

5.2.1. **Organ Transplantation Breakthrough Collaborative**: launched in April 2004 with the expressed aim to *" Save or enhance thousands of lives a year by maximizing the number of organs transplanted from each and every donor…"*

[g] For complete CMS interpretation of their regulation pertaining to organ donation, see Appendix B.

[h] Letter sent to the NEOB regarding the Memorandum of Understanding, see Appendix C.

The OPOs and transplant centers are engaged in an intensive series of collaborative learning sessions in an effort to redesign procedures and educate staff at centers about the importance and life-saving benefit of organ donation. CHB has named Drs Heung-Bae Kim and Jeff Burns as designees to the Collaborative.

5.2.2. In 2004, the Health Resources and Services Administration (HRSA) and the Greenwall Foundation asked the **Institute of Medicine** to study issues surrounding organ donation with a specific focus on improving the rates of organ donation. This third IoM report, titled ***"Organ Donation: Opportunities for Action"*** was published in May 2006[4], and concluded that:

> *"the current system can be greatly improved…a number of specific recommendations should help increase the supply of transplantable organs, saving lives and improving the quality of life for many people who need new organs."*

This recently published IoM report is a result of a 16 month study conducted by a committee composed of experts in the fields of bioethics, law, health care, organ donation and transplantation, economics, sociology, emergency care, end of life care, and consumer decision making. The fundamental conclusion contained in the report is the goal to move toward a society where people see organ donation as a "*social responsibility"*, *i.e.,* the donation of organs be accepted as a normal part of dying, and in cases where a person died without recording a specific choice about donating his or her organs, the family members would be comfortable giving permission. It was also noted that efforts to change societal attitude should precede legislative moves aimed at increasing organ donation, such as enacting a policy of mandated choice or a policy of presumed consent.

The broad recommendations from the report for clinical practice included:

- *Sustain continuous quality improvement initiatives,*
  This includes dissemination of best practices and for individual OPS and transplant centers to develop, implement and evaluate quality improvement processes, with oversight from Association of Organ Procurement Organization, JCAHO, National Committee for Quality Assurance (NCQA), HRSA, Centers for Medicare & Medicaid (CMS) and private insurers.
- *Increase research on innovative system changes;*
  This includes identifying further innovative and effective system changes to increase the rates of organ donation, and study this impact on the health care system
- *Strengthen and integrate organ donation and quality end-of-life care practices,*
- *Enhance training for healthcare professionals,*

The goal is to establish a knowledgeable and positive environment that supports organ donation.

The IOM committee recognized that the increased procurement of organs from DCD patients could expand the population of potential donors. They cite "one conservative estimate" suggesting at least 22,000 out of hospital cardiac arrest deaths annually in the USA could be potential donors if important ethical and practical matters could be resolved (although this reference has not been cited nor claim substantiated). The intent is clear, however, which is to increase uncontrolled DCD. Their recommendations to expand the donor pool included:

- *Implement initiatives to increase rates of donation after circulatory determination of death:*
  - *Funding of interdisciplinary research*
  - *Enhancing public and professional education*
  - *Clarify required referral regulations*
  - *Add preparation for organ donation to the end of standard resuscitation protocols*
- *Encourage and fund DCDD demonstration projects,*
  Primarily to determine the feasibility of increasing the rate of uncontrolled DCD.
- *Maintain opportunities for organ donation,*
  Primarily by seeking community approval to start postmortem organ preservation techniques during the time needed to seek family consent.
- *Increase research on organ quality and enhanced organ viability.*

To promote and facilitate individual and family decisions to donate organs, the report made the following recommendations:

- *Increase public understanding of and support for organ donation*
- *Increase opportunities for people to record their decision to donate*
- *Enhance donor registries*
- *Mandated choice should **not** be enacted*
- *Presumed consent **not** to replace the existing legal framework at this time, which requires explicit consent unless otherwise specified.*
- *Financial incentives should **not** be used to increase the supply of transplantable organs*
- ***No** preferential access or status for a potential recipient of organs from deceased donors*

While the IoM committee considered ethical questions regarding living donors, the ethical concerns related to donation after cardiac death were not emphasized and no specific recommendations included in the report.

This latest IoM report regarding opportunities for action to improve organ donation was published after the deliberations of the Task Force had been completed. As it turned out, however, all of the recommendations for clinical practice in the IoM report had been considered by the Task Force and are enclosed in the sections on *"Pros and Cons of DCD"* and *"Protocol for DCD"*. Specifically, this included quality improvement initiatives including integration of the organ donation process

with quality end of life care practices, development and training for interdisciplinary teams, enhancing public and professional education and development of interdisciplinary research. Of note, the IoM report concentrates on research regarding organ quality and enhanced organ viability, and not specifically on the ethical issues surrounding donation after cardiac death.

In all of the IoM reports, there was no specific discussion of pediatric DCD. Throughout the comprehensive 2006 report for example, there were only 20 references to the word "pediatric" and 35 references for the word "child". Although pediatric concerns were not the focus of the reports, and it is likely there was at least some discussion regarding pediatric transplantation at the committee level, the differences and considerations unique to pediatric DCD deserve specific reference and acknowledgment by transplant organizations, federal agencies and regulatory bodies. This concern was expressed throughout deliberations by the Task Force. These unique differences are outlined in *Pros and Cons of DCD*, and relate to important issues in pediatrics, such as greater prognostic uncertainty for any type of neurological recovery in a pediatric patient and therefore the decision making surrounding withdrawal of life support, conflicts of interest between withdrawal of life support and organ donation, decision making between staff and families as well as organ procurement organization and issues surrounding public faith and trust.

5.2.3. The **Joint Commission on Accreditation of Healthcare Organizations** (JCAHO) has developed an accreditation requirement that all hospitals work with their local OPO to evaluate DCD potential and establish a protocol where applicable. (see http://www.jointcommission.org/PublicPolicy/organ_donation.htm)

In a white paper emanating from the Joint Commission's new Public Policy Initiative: "*Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients"*, a Roundtable of experts made recommendations to:

- *Create a Culture in Which Organ Donation is a Priority*
- *Bring Equity, Fairness and Safety to the Transplantation Process, and*
- *Take Alternative Paths to Meet the Demand for Organ Donation.*

In this last recommendation, the implementation of protocols for the recovery of organs from donors after cardiac death is specifically stated. The JCAHO standards for hospital accreditation mirror the requirements stipulated in CMS regulation §482.45 (see above), and emphasize the importance of accreditation to increase donor conversion rates. We will be required to continuously measure, assess and improve organ donation conversion rates, which must require close collaboration with NEOB. One overarching principle from JCAHO is the integration of organ donation fully into routine roles and responsibilities, and they emphasize the importance of leadership commitment, from the top down, to create a culture supporting all forms of donation.

5.2.4. The Organ Procurement Organization Committee of the **Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS)** recently secured proposed a change to the OPTN bylaws, such that:

> ”*all OPTN member organizations, OPOs and transplant hospitals must develop by January 1st 2007, [and once developed must comply with] protocols to facilitate the recovery of organs from DCD donors.”*

The bylaw includes “required referral”, in that no hospital has the discretion to refuse permission for the OPO to discuss organ donation with the family of a dying patient. The Pediatric Transplantation Committee of the OPTN considers medical, scientific and ethical issues relating to organ procurement, allocation and sharing for pediatric patients, and discussed in detail the proposed Bylaw change.[i] There is no specific reference to pediatric DCD written in the change to the Bylaw, but may reflect that they don’t consider pediatric DCD to be substantially different from adult DCD. Nevertheless, the issue of pediatric DCD is an important one, with some stand alone pediatric hospitals and pediatric intensivists expressing interlocking concerns that may not be shared by adult institutions and staff. The changes to the Bylaw are not yet final and subject to change after a public comment period that ended late October. The degree to which this mandate would be enforceable in the face of well-grounded medical concerns, or enforced in such circumstances, is subject to debate.

The co-chairs of the Task Force, Charlotte Harrison and Peter Laussen, posted a response to the proposed Bylaw change during the open public commentary period.[j] Their comments principally requested deferral of the requirement by pediatric institutions for implementation of a DCD protocol by January 1 2007, until further information, discussion and consensus are obtained. The Pediatric Subcommittee of the OPTN deliberated upon this issue and has recommended pediatric DCD be deferred as long as a hospital demonstrates it has a plan and a specific timeline for putting a pediatric DCD protocol in place.[k] The Subcommittee also supported the concept of a consensus conference for pediatric DCD, and a session on DCD has been requested within the ethics program at the forthcoming World Congress on Pediatric Intensive Care, June 2007.

5.2.5. The **Massachusetts Donor Registry**, established by statute and implemented through agreement between the Massachusetts Registry of Motor Vehicles (RMV) and the NEOB, has been activated in 2006. The RMV will enter names of individuals who designate themselves as donors at the time of licensure or renewal into a database accessible to the New England Organ Bank on a 24-hour/ 365-day-a-year basis. When a hospital within Massachusetts makes a referral regarding a potential donor to the New England Organ Bank, the Donor Registry database will be searched to determine whether that individual had made a donor designation. Further

[i] Personal communication, Dr. William Harmon

[j] Comments submitted to the OPTN by co-chairs of the Task Force, see Appendix D.

[k] Response letter from Pediatric Transplant Committee of UNOS, Appendix E

amendments were made securing the irrevocable rights of adult individuals on the donor registry to donate their organs. Importantly, however, this act does not change the legal requirement that a donor be 18 years old or older. Thus a minor who has designated himself or herself as a donor on a driver's license may not donate without the consent of a parent or other legally authorized representative. In addition, at Children's Hospital's request, the legislature in passing this act specifically removed language which would have expanded the state donation requirement beyond the scope of federal mandates.

While the enactment described below is the state policy supporting organ donation in general, it is not a legislative resolution of the DCD question in pediatric cases.

"FURTHER REGULATING ORGAN AND TISSUE DONATIONS.

Whereas, The deferred operation of this act would tend to defeat its purpose, which is forthwith to further regulate organ and tissue donations, therefore it is hereby declared to be an emergency law, necessary for the immediate preservation of the public health and convenience.

Chapter 145 of the acts of 2005 is hereby amended by striking out section 5 and inserting in place thereof the following section:-
Section 5. Section 8 of said chapter 113, as appearing in the 2004 Official Edition, is hereby amended by striking out subsections (b) to (g), inclusive, and inserting in place thereof the following 5 subsections:-

(b) An organ or tissue donation, regardless of the document of gift making such donation, that is not revoked by the donor before death shall be irrevocable and shall not require the consent or concurrence of a person after the donor's death.

(c) On or before the occurrence of death in an acute hospital, the federally-designated organ procurement organization or federally-registered nonprofit eye or tissue bank shall, subject to hospital protocols consistent with applicable federal laws and regulations, inform any of the persons listed below in the order of priority stated when persons in prior classes are not available if the decedent authorized a gift or, if the deceased failed to authorize a gift, of the opportunity to authorize a gift of all or part of the decedent's body for purposes of organ and tissue transplantation as provided in section 9, if no actual notice of contrary intentions by the person has been received and if consent to such donation could yield an organ or tissue suitable for transplantation. The order of priority of such persons shall be:-

(1) spouse;
(2) an adult son or daughter;
(3) a parent;
(4) an adult brother or sister;
(5) a health care proxy;
(6) a guardian of the body of the decedent at the time of his death; and
(7) any other person authorized or under obligation to dispose of the body.

(d) If the donee has actual notice of contrary indications by the decedent, or that a gift authorized by a member of a class is opposed by a majority of individuals in the same or a prior class, the donee shall not accept the gift. A person authorized in subsection (c) may make the gift after death or immediately before death.

(e) A gift of all or part of a body authorizes premortem tests and any other examination necessary to assure medical acceptability of the gift for the purposes intended by the donor.

(f) The rights of the donee created by the gift shall supersede the rights of others except as provided in subsection (d) of section 13.

This act shall take effect as of November 22, 2005."

5.3 RELATIONSHIP BETWEEN CHB AND NEOB

UNOS and organ procurement organizations have a direct mission to save lives by increasing the number of organ donations. They are committed to this important objective, are well organized and funded, and have legal requirements and regulatory support for their mission. As such, any successful and active transplant center must have a trustworthy and collaborative relationship with their affiliated OPO. Such a relationship does not always exist at CHB, and improvement in this area is an essential step to developing a viable DCD program.

Concerns were expressed by the Task Force and during focus groups, that undue pressure interfering with patient management and decision making by the NEOB requestors could have an adverse effect on patient care. The intensivists in particular cited examples where perceived interference in patient care by organ requestors has led to undue pressure and conflict. It is important that respect for the autonomy of clinicians at CHB be protected, and that at the same time, respect and collaborative practices with the NEOB be developed. It was not possible during Task Force deliberations to determine how this may be achieved, or even where the root cause for this conflict arose in the first place, but it is sufficient to say that a DCD program will not succeed unless changes occur.

The Task Force was told that, in the past, meetings have been held between CHB ICU staff and the NEOB. The Task Force did not include participation from NEOB staff during the Phase 1 discussions, although 2 members of the Task Force were also members of the NEOB Board; rather, data from UNOS was presented, including current trends for DCD in the New England region. During the Phase II protocol development, a NEOB director (Kevin O'Connor) was invited to actively contribute to protocol development and he actively contributed to Task Force discussions at several meetings. The NEOB Director agreed with the protocol provisions outlined in sections 2, 3 and 4, including developing a list of contraindications for DCD, streamlining initial contacts with NEOB, ICU staff and the family, improving the relationship between NEOB and CHB ICU staff, and committing to select NEOB staff to work with CHB staff when organ donation was being considered.

The working relationship between the NEOB and the Task Force during protocol development was constructive and mutually respectful. While the protocol provides ground rules for NEOB involvement, the Task Force recognized the need for improved and sustained collaboration on the floor of the ICUs, and felt that this should be initiated from the executive level at both CHB and the NEOB.

5.4 TASK FORCE CHARGE

There are significant differences between adult and pediatric patients with respect to withdrawal of care, including the rights and advocacy of parents and families for their children and the ethical and emotional factors surrounding the process of withdrawal of care. Rather than adapt a protocol from existing adult-based protocols, the Chief Executive Officer, the Vice President for Patient Care Operations, and Medical Staff Executive Committee at Children's Hospital Boston viewed developing a DCD protocol as an institutional concern. As such, a multidisciplinary Task Force was established to first determine whether a DCD policy was consistent with the mission of the Children's Hospital (Phase I), and if that determination was affirmative, to develop a DCD protocol for use at the hospital (Phase II) and recommend a process for implementation (Phase III). Co-chaired by an intensive care physician and member of the hospital Office of Ethics, the Task Force included broad representation of members across hospital disciplines that had a potential stake-holding in organ transplantation. Members represented the Parent Resource Center, critical care nursing and medical staff, nephrology, transplant surgery, anesthesia, respiratory therapy, ethics, pulmonology, neurology, social work, operating room nursing, palliative care, pastoral care, and the hospital legal counsel. In addition, there was one public member, who serves on CHB advisory boards but is not on the Hospital staff.

SECTION II

PHASE I

1. **WORK PLAN**

3. **INDIVIDUAL REPORTS**

4. **SUBCOMMITTEE REPORTS**

5. **SUMMARY OF PHASE I & FOUNDATIONS FOR PEDIATRIC DCD AND MOTION PRESENTED TO THE MEDICAL STAFF EXECUTIVE COMMITTEE**

SECTION II

PHASE I

The work plan during Phase I included plenary meetings of the full Task Force with presentations of reports from individuals and subcommittees as summarized below.

1. WORK PLAN

1.1 PLENARY MEETINGS:

Nine plenary meetings of the full Task Force (1-1/2 to 2 hours each) were held.
Dates and agendas included:

Feb 9:	Charge & Introduction to DCD & review of 1997 and 2000 Institute of Medicine reports
Mar 9:	Ethical Debates & Legal Issues
Mar 18:	DCD at Children's Hospital of Philadelphia (Dr Sarah Hoehn)
April:	no plenary meeting; offline subcommittee research and report preparation
May 4:	Updates, Ethics Frameworks, Financial Implications, Consensus Process
May 9:	Public Opinion / 60 Minutes & DCD
May 18:	Family, Community & Public Views of DCD
May 25:	Religious Values & Views of DCD
June 1:	CHB Staff Views; Other Institutions' Policies & Experience
June 8:	Final Deliberations & Recommendation

1.2 SUBCOMMITTEE RESEARCH:

Task Force subcommittees undertook the following research projects:

1.2.1 Numbers and clinical profiles of DCD candidates at CHB: Analysis of ICU deaths at CHB 2002-2004 as a basis for projecting the numbers and clinical profiles of likely DCD candidates at CHB in the future.

1.2.2 Values and attitudes toward DCD of CHB staff: Focus group discussions with 8 groups of CHB staff, including MSICU, CICU and OR nurses, CICU and MSICU physicians, anesthesia, pediatric surgeons and respiratory therapists.

1.2.3 Policies, protocols, experience and views of DCD from other pediatric institutions: Structured phone interviews with 17 pediatric institutions and centers across the US.

1.2.4 Values and attitudes of families, the community, and the general public: Research into family and public attitudes toward DCD, including a review of

scholarly literature and popular press/Web/TV commentary about DCD and literature on parent and public attitudes toward organ donation in general.

1.2.5 Financial implications for the institution and families: Preliminary review involving NEOB and CHB Finance.

1.3 ADDITIONAL DATA COLLECTION AND REVIEW:

A. Review of available **UNOS data** from their website and relevant literature regarding the frequency of DCD across centers and OPOs in the USA, indications for DCD, and the short and longer-term outcomes of the function of transplanted DCD organs and patient survival).

B. Attendance by 2 Task Force members at a **National Consensus Conference** focusing specifically on DCD (Philadelphia, April 7-8 2005); proceedings published in the American Journal of Transplantation 2006.

C. **Invited lecture** by an intensive care attending physician regarding the DCD program at Children's Hospital of Philadelphia.

D. Review of **ethical and legal issues** in the context of the literature on DCD and the organizational culture of CHB.

E. Review of **religious values and views** of DCD, presented by CHB chaplaincy members Rabbi Susan Harris, Father Robert Nee, and Task Force member Rev. Mary Robinson.

Some of these reviews are reflected in the individual reports directly below. Others are incorporated into Sections I and IV of this report.

2. INDIVIDUAL REPORTS

2.1 REVIEW OF PEDIATRIC ORGAN TRANSPLANTATION

Dr. William Harmon MD, Chief, Division Nephrology

Boston medical centers have been at the forefront of innovations in organ transplantation for the past half-century. The first successful organ transplant was a kidney transplant performed between identical twin brothers at the Peter Bent Brigham Hospital on December 23, 1954. This occurred during an extraordinary period of clinical investigation at that institution. The same team was responsible for developing the initial immunosuppressive medications that made less closely matched living donor transplants possible and which eventually led to the general availability of cadaver donor organ transplants. Concern about the use of cadaver donors eventually led to the Harvard criteria for declaring a potential "brain-dead" which, in turn, led to more controlled and less hectic organ recovery techniques.

Recognizing the need for cooperation between academic medical centers and community hospitals for identification of these potential organ donors, the New England Organ Bank was formed, becoming the first multi-institutional Organ Procurement Organization in the United States. The New England Organ Bank has been highly innovative and has served as a model to the rest of the transplant community in many ways. It is widely recognized as having the widest sharing of kidneys for transplantation in the United States and it is responsible for having the only region-wide kidney sharing system in the country. It led the country in assuring region-wide sharing of livers for transplantation. It was the first OPO in the United States to develop a system of living-donor/deceased donor "swaps" and the first to provide a region-wide system living-donor swaps. It is the first OPO to have an established DCD program shared by all of the participating transplant hospitals.

Children's Hospital Boston has been involved in many innovative programs throughout these years. Currently, CHB is involved in more innovative NIH-sponsored kidney transplant immunosuppression research protocols than any other hospital in the USA and has been responsible for developing the majority of them. CHB was the one of the first two institutions to undertake a living-donor swap through the NEOB. CHB participated in the NEOB Non-directed living donor program and accepted a donor who had no preference for a specific transplant center (the NEOB rules allocated the donor to the highest-ranking child on the list). CHB historically has had very high "conversion rates" of potential deceased donors, often being the highest in the NEOB. CHB was the first hospital in New England to offer "Organ Donor Leave" to its employees.

Children's Hospital Boston has been slow to adopt a Donation after Cardiac Death protocol and is the only organ transplant hospital in NEOB to not have one. This committee has been established to examine that issue more carefully. In that context, it is important to understand that the transplant teams certainly champion the expansion of organ donation efforts in general, but avoid personal involvement in potential donors. Thus, although we discuss living organ donation with potential donors, we transfer them to independent advocates once they have indicated a willingness to consider donation. Similarly, the organ transplant teams do not

participate in interactions with potential deceased donor families. Thus, the role of these teams in the discussion of DCD protocols could be considered a conflict of interest in many ways. However, it is also true that these protocols must have institutional and professional support in order to be meaningful and appropriate. Thus, the teams certainly have a role to play in developing the protocols, without advocating directly for potential recipient issues.

It should also be noted that any DCD donors recovered at CHB will not be used for CHB kidney transplants, at least initially. There is broad concern about the quality and suitability of these organs for long-term outcomes, because of the perfusion damage at the time of recovery. While some are clearly excellent, others do not function early on and may have substantial damage. Thus, recipients of these organs likely should be told of the source and probably should agree to that source. In that manner, these are likely similar to "extended criteria donors" who are rarely used for children. Furthermore, children less than 18 years of age have priority for deceased donors throughout the region and, thus, they don't really "need" these donors to be successfully transplanted. It is possible that the donors may be used for liver or lung transplantation, but, again, children awaiting those transplants have preference to other deceased donors throughout the region. The motivation for supporting DCD protocols, therefore, should be much more that of sustaining the organ supply for the transplant community in general rather than for our own self-interest in increasing the potential organ donor supply only for our own patients.

2.2 REVIEW OF LEGAL ISSUES:

Patrick L. Taylor BA JD, Associate General Counsel

The public policy imperative to promote organ donation for transplant is reflected in many changes in federal and state law to foster donation, including:

- the creation of the OPTN and UNOS
- coverage by governmental and other payers for organ transplantation
- the funding and creation of registries related to organ transplantation
- required notification of deaths and required referrals to organ procurement organizations
- adoption by the states of the uniform anatomical gift act

Despite all of those changes, certain things have not changed.

Attending physicians still owe an undiluted and single-minded duty of care to their patients, which may not be compromised by conflicts of interest. This is reflected, for example, in legal requirements that patients and families be approached for donation by OPO staff independent of the attending who will declare death.

The basic medical and ethical standards that should govern end-of-life care in the ICU or elsewhere are also undiluted by the potential for organ donation. Absent consent, it is illegal to perform interventions on a patient solely to further organ donation. Even consent would not suffice for surrogate consent situations in which the harm to the patient from procedures solely to promote organ preservation and donation could not be ethically defended, nor of course can a person consent, for themselves or others, to actions which would violate the "dead donor rule."

In MA, the premortem gift of a body for donation authorizes premortem tests and examinations to determine medical acceptability, but the statute so stating stops short of implying authorization for premortem interventions designed solely to preserve the organs. That does not mean that the law excludes premortem consent for cannulation and similar procedures, but it means that patient consent, and especially surrogate consent, for such procedures lies in a gray area in which the best legal defense will be well documented adherence to highest clinical and ethical standards concerning obtaining consent to such procedures and their appropriateness. The lack of clarity in the law here (as distinguished from regulations or laws that would clearly authorize such procedures prospectively) means that judgments about interventions that potentially decrease lifespan, or potentially increase pain, or otherwise create some appearance of hastening death or altering the course of death will be judged in retrospect through the prism of a jury's eyes under the extremely inchoate standards of a malpractice action, and one must be watchful of situations in which consenting parents regret their consent based on the actual course of events being different than what they expected. The ultimate reference point for such a decision is the competing expert views present in academic and medical literature, and peer processes such as the Task Force's own efforts, as viewed by the jury through a case which will probably have been to some degree sympathetic in its facts to have been brought.

In MA, the declaration of death for purposes of organ donation is referred by regulation to 'currently acceptable medical criteria', including brain death, while brain death is defined, under

case law, as ‘total and irreversible cessation of spontaneous brain functions and further attempts at resuscitation or continued supportive maintenance would not be successful at restoring such functions’. These definitions, however, do not end the discussion, they merely start it, for they do not answer the questions that the IOM and other reports and literature struggle with. Death, of course, does not end the period in which consent is required to act upon a body, for even then the common law ‘quasi property rights’ of relatives to determine the disposition of a body, and the statutory provisions of the uniform anatomical gift act, require consent of next of kin in a designated order for organs to be removed for donation.

The bottom line is that any policy should provide for effective consent for donation that meets appropriate ethical and clinical standards; that the care of patients before death is driven by undiluted service to their care; that practical conflicts between care and surrogate consent to donation need to be minimized and ethically addressed, with some careful skeptical review given to surrogate consent to premortem steps that while promoting donation may potentially harm the patient or the patient’s care; that clinicians’ and hospital conflicts of interest have to be completely avoided; and that the test for whether we can both serve the important goal of promoting organ donation and meet these standards should be a hard-nosed pragmatic one – as hard-nosed as a jury’s review of a case in retrospect – about whether Children’s can establish a way of doing it in this institution, in its specific care environment, which will in a consistent, documentable fashion show that we have done so.

2.3 RELIGIOUS ISSUES IN DCD

Rev. Mary Robinson, M.A., M.Div., Director of Chaplaincy

Many critical religious objections remain unresolved in the "best possible DCD protocol." Some crucial beliefs and unresolved concerns are summarized here:

Children, like the sojourner, widow, the prisoner and orphan, are a vulnerable population. Sick children are the most vulnerable of the vulnerable. We have unique obligations to incompetent and never competent children who are mortally ill and powerless. Thus standards for a dying child's protection, care and best interest ought to be higher than the standards for routine pediatric care or competent adults

Terminal illness, age and medical frailty do not diminish personhood. Interventions that benefit the organ or the recipient of the organ are prohibited as they treat the dying child as a container of organs rather than a person who is dying. Nuremburg and Tuskegee remind us that we must always be vigilant in protecting the personhood of the patient.

All care must directly benefit and comfort the dying child. Transporting the dying patient, replacing a familiar and comforting environment of dying with an OR setting, changing the care team at the end of life, *any* medical interventions for the benefit of transplantation, even with parental consent, are offensive and prohibited.. An estimated forty-two percent of our donors will not die within 60 minutes of withdrawal of life support, and thus those dying children would be transported a second time back to the ICU setting. Some of these children could conceivably die in transit, in elevators and hallways. If they arrive back to the ICU, little is known of how a failed DCD donation will impact the patient and parental experience of the end of life.[1]

DCD fails the Double Effect test. The person who suffers potential harm (the dying child) must also be the beneficiary of the intended resulting good (donated organ; psychological comfort of altruism) The harvested organs do not benefit this dying child, and are unlikely to benefit the class of dying children awaiting organ transplantation. Any psychological benefits would go to the parent, not the patient. DCD passes the Double Effect Test only if the donor is a fully informed, consenting and competent patient. Thus DCD is better suited to an adult hospital than pediatric setting.

This protocol is likely to create spiritual and moral distress for CHB caregivers. While staff member may theoretically ask to be excused from DCD, this would present a dilemma for small departments. Four of our six chaplains (66%) have expressed serious reservations about participating in this protocol. We lack on-call back-ups for this protocol. Chaplains would then have to choose between abandoning patients to whom they have given spiritual care, explaining why they are no longer available, or providing care in violation of conscience. Asking community clergy who lack hospital, pediatric and DCD training to fill in is not an option.

[1] See Appendix A.

The deliberations of the DCD Task Force have been lengthy, heated and at times disrespectful, in spite of thoughtful leadership. Were we to activate this protocol in the climate of deeply felt spiritual and moral disagreement, collegial relationships in care teams are likely to be damaged.

3. SUBCOMMITTEE REPORTS

Each subcommittee conducted separate meetings and research before reporting to the full Task Force, on the following topics:

3.1 POSSIBLE NUMBER OF CANDIDATES FOR DCD AT CHILDREN'S HOSPITAL:

Committee members: Adrienne Randolph (Chair), Amy Durall, Peter Laussen

ICU deaths at CHB between 2002-2004 were examined as a basis for projecting the number and clinical profiles of likely DCD candidates at CHB in the future.[m]

All 254 deaths in the Medical/Surgical Intensive Care Unit (MSICU) and the Cardiac Intensive Care Unit (CICU) from 2002-2004 were reviewed, and potential DCD kidney donors identified, Figure 5. Those patients who died but did not did not qualify as brain dead were stratified according to age with those less than three months of age being excluded because of size limitations of the vessels for renal transplantation. After stratification by age, the patients were further subdivided into those for whom life sustaining treatment was withdrawn and those who experienced a cardiopulmonary arrest. Those who had life sustaining treatment withdrawn continued to fulfill the criteria for potential DCD donation and were further stratified according to suitability for renal transplantation assessed by serum creatinine level (less than 1.5 mg/dl), urine output, blood pressure measurement, and oxygen saturation prior to withdrawal of medical treatment. Patients were declared ineligible for DCD if they met criteria as outlined in the previous study from CHOP, but in addition, the time from withdrawal of support to declaration of death was limited to one hour, a generally used standard for organ viability in established DCD. Based on these criteria, only 14 of 254 deaths (5.5%) would have fulfilled criteria for DCD. During this three year period, there were eight families who consented to organ donation based on brain death or heart beating criteria, a consent rate of 47%. Therefore if we had had a DCD protocol active over this three year period, and assuming a similar consent rate, this would have yielded an additional seven organ donor patients over this time frame. It is recognized that these numbers are small and the potential ethical, legal, and emotional concerns related to instituting a DCD policy must be weighed against the relatively small increase in the donor pool.

[m] For full manuscript, "Potential for Donation After Cardiac Death in a Children's Hospital" (accepted for publication in *Pediatrics* 2007), see Appendix A.

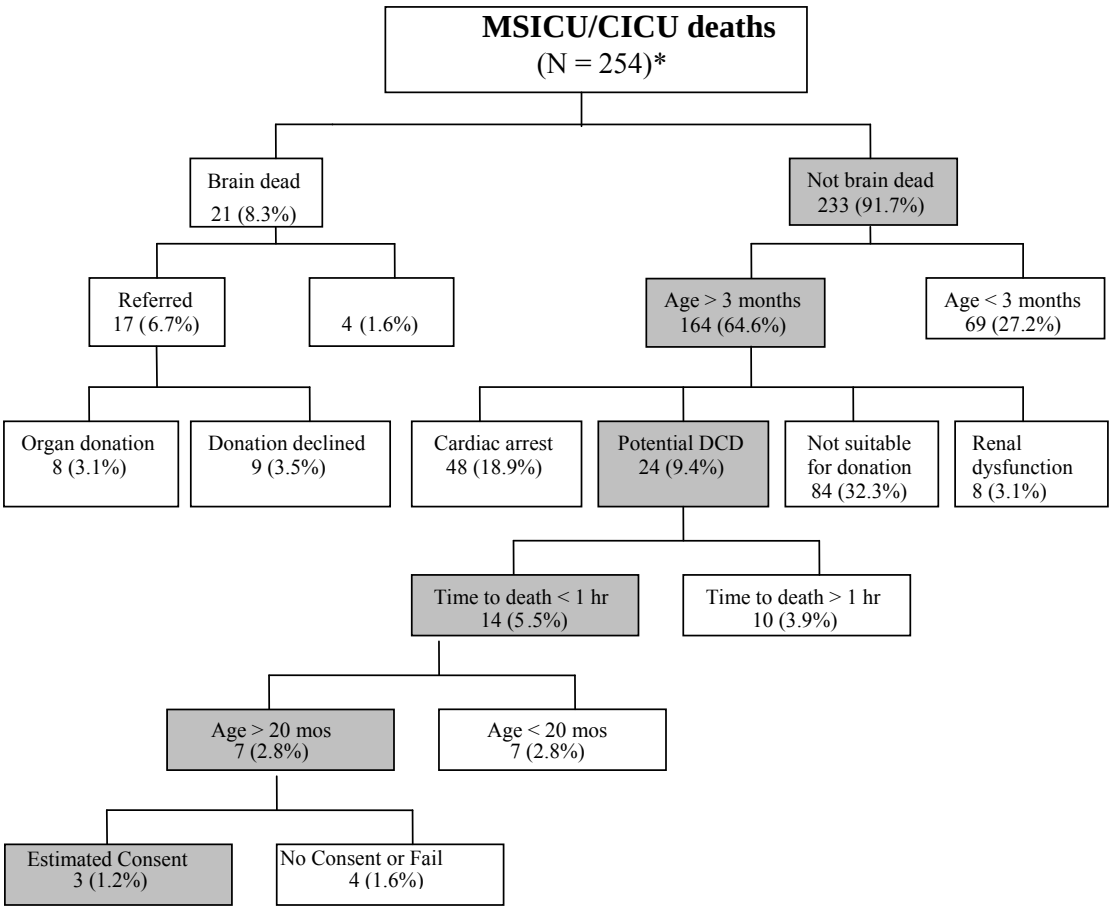


Figure: MSICU/CICU deaths 2002-2004 and potential for DCD. Percentages are of the total number of patient deaths. *Percentages are of total number of deaths.

3.2 VALUES AND ATTITUDES TOWARD DCD BY STAFF AT CHB:

Committee members: Martha Curley (Chair), Nancy Craig, Craig Lillehei, Anne Micheli, Charlotte Harrison, Peter Laussen

The process of donation after cardiac death involves multiple disciplines, including intensive care physicians and nursing staff, transplant physicians and nursing staff, the organ procurement organization, operating room personnel and support staff including anesthesia, respiratory therapy, and pastoral care services. The withdrawal of life support during donation after cardiac death usually occurs within the operating room, and as such the environment and process by which withdrawal of life support takes place is substantially altered.

We designed a *qualitative study* to provide the Task Force with an internal perspective on donation after cardiac death in children. Our primary objectives were to gather the views of pediatric clinicians on whether or not a DCD program could be consistent with the mission and core values of our institution, and to identify the specific considerations that would be essential to determining the acceptability of such a program. Because DCD involves numerous disciplines beyond those traditionally involved in the withdrawal of life support within the intensive care unit, and because of the significance of potential concerns regarding the process of DCD, we sought the opinions of a range of staff who would be directly affected by a DCD program.

Focus group discussions were held with 8 groups of CHB staff, including intensive care and operating room nurses, intensive care physicians, anesthesia, pediatric surgeons, respiratory therapists, and pastoral care staff, and was conducted from March-April 2005. Focus group participants were purposively sampled to represent the clinical disciplines and subspecialties that would be involved with a donation after cardiac death program. The clinician perspectives on donation after cardiac death in children were measured. Eighty-eight staff with an average of 17 ± 10 years of pediatric experience participated.[n]

[n] For full manuscript, "Pediatric Staff Perspectives on Organ Donation after Cardiac Death" (accepted for publication in *Pediatric Critical Care Medicine*, 2007), see Appendix F.

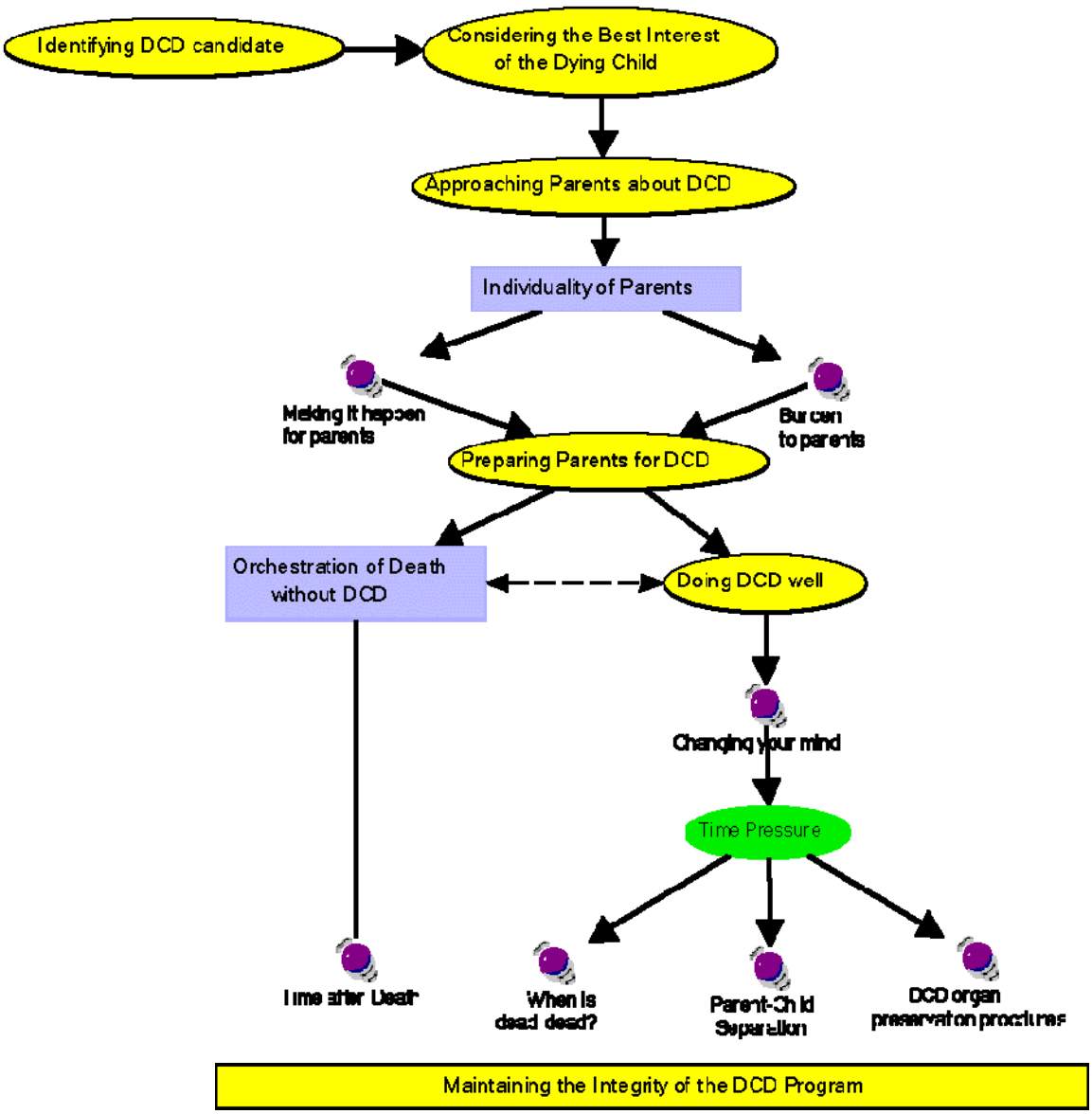


Figure: Donation after cardiac death conceptual model.

Staff concerns focused on six major themes: 1) identifying children who could be candidates for donation after cardiac death; 2) considering the best interests of the dying child; 3) approaching parents about donation after cardiac death; 4) preparing parents for their child's donation after cardiac death; 5) the need to do donation after cardiac death well; and 6) maintaining the integrity of a donation after cardiac death program. The themes were used to construct a conceptual framework that describes an idealized pediatric donation after cardiac death program, Figure 6. Pediatric clinicians voiced numerous concerns about the design of a donation after cardiac death protocol. However they identified "making it happen for families" as the primary reason for protocol adoption.

3.3 PROTOCOLS & EXPERIENCE OF DCD FROM OTHER PEDIATRIC INSTITUTIONS:

Committee members: Peter Laussen, Robert Truog, Nancy Craig, Amy Durall

Structured phone interviews with 19 pediatric institutions and centers across the US were conducted by 4 Task Force members in April-May 2005.

Representatives from the pediatric intensive care units at 19 pediatric hospitals across the USA were surveyed by telephone as to whether or not their hospitals permitted donation after cardiac death for pediatric patients. A standardized questionnaire was used for each interview (see Appendix F). One institution that had performed the highest number of pediatric DCD procedures did not have a specific protocol. Only three institutions had developed protocols primarily for pediatric patients, and while in all cases withdrawal of life support was undertaken in the operating room, there was variability as to the period from withdrawal of support to acirculation and the subsequent wait period to determine whether autoresuscitation occurred. Six institutions permitted DCD for pediatric patients but used adult protocols. In all circumstances, the withdrawal of treatment occurred in the operating room. At one of these institutions, all of the families of potential DCD candidates were approached, whereas at three other institutions, DCD was only initiated when specifically requested by the family. Three institutions were in the process of discussing whether or not they would permit DCD, and four institutions did not permit DCD in children for ethical and clinical concerns regarding end of life care and determination of death.

The comments from the institutions that undertook pediatric DCD were quite varied. At two institutions (Wisconsin and Cincinnati) where there was an established adult DCD program and a favorable relationship with local organ procurement organizations, DCD for pediatric patients had proceeded smoothly. Other institutions who utilized an adult protocol for pediatric patients commented that the process was painful for staff although worth it for families, that the operating room environment needed to be user friendly, and that there were significant emotional shifts for staff and potential for conflicts of interest.

At the time of the telephone interviews, none of the institutions surveyed had undertaken a rigorous review such as by this Task Force, and there are no established or thorough protocols to guide the development of pediatric DCD at Children's Hospital. The protocol subsequently developed is unique for this institution.

Addendum: Over the course of the past 16 months, the co-chairs of the Task Force are now aware of 4 pediatric specific protocols that have been developed, including Morgan Stanley Children's Hospital NY, LA Children's Hospital, Seattle Children's Hospital and Children's Mercy Hospital in Kansas City.

3.4 VALUES AND ATTITUDES OF FAMILIES AND THE COMMUNITY

Committee members: Meg Comeau (Chair), David Coulter, Roberta Hoffman, Patti Kraft.
Staff: Charlotte Harrison, Michelle Hogle

Research was conducted into family and public attitudes toward DCD, including a review of scholarly literature, popular press/Web/TV commentary about DCD and literature on parent and public attitudes toward organ donation in general. Discussions centered around 4 major areas and are expanded upon in the *Pros and Cons of DCD* section below.

- *The dying patient:* What constitutes a 'good death' for pediatric patients? What are the essential elements of a 'good death'? How are decisions made to withdraw support? How would a DCD protocol change our end of life care? Effect on dying patient? Are there ways to adapt DCD protocol to respond to concerns? What are our obligations to potential recipients?

- *The families of dying patients*: Would DCD help or hinder families' grief process? Is there risk to trust in care providers? How can we mitigate risk? Is risk to trust higher in families from minority communities? Risk of discrimination in certain adaptations? Are the emotional needs of the family being places ahead of the needs of the patient? Best interest and substitute judgment problematic in DCD-are there other ethical standards that can be used to help families in their decision-making? If we vote 'no', what is the burden on families?

- *The general public*: Potential concerns of the public? Risks to public trust in CHB or the organ donation system? If a 'yes' vote on DCD, how can public understanding and acceptance be maximized?

- *CHB as an organization*: Would DCD be in keeping with the Hospital's mission? What is our obligation as a leader in pediatric medical innovation? What are the benefits versus risks in terms of patient, family and general public trust?

Acknowledgments: The subcommittee thanks the following CHB staff members with whom we consulted: Michelle Davis, Elaine Meyer, and Anne Speakman.

3.5 FINANCIAL IMPLICATIONS FOR THE INSTITUTION AND FAMILIES:

Committee members: William Harmon, Patrick Taylor

The financial considerations subcommittee, composed of William Harmon and Patrick Taylor, met with 3 representatives of the New England Organ Bank (NEOB) on April 5, 2005 to review the financial considerations of a DCD protocol at Children's Hospital Boston. These 3 were Richard Luskin, Executive Director of NEOB, Kevin O'Connor, Director of Donation Services of NEOB and Dara Washburn, Director of Finance for NEOB. In addition, Steven Nicoll and Kevin Kilday from CHB Finance attended the meeting.

The financial considerations of Brain Dead Donors (BDD) was first reviewed. The current financial support of BDD is designed to assure that donor hospitals and donor families bear no financial responsibility or penalty for organ donation. Thus, all procedures, tests and other costs for supporting the potential donor after declaration of brain death are assumed by the Organ Procurement Organization (OPO) which is the NEOB for CHB. In general, the OPO will not assume costs otherwise appropriately covered by the donor's insurance (*e.g.,* day-rate for the ICU for the day during which brain death was declared), but will support appropriate costs for organ donation above and beyond coverage by insurers with DRGs. The NEOB assists the donor hospital in identifying these costs and will reimburse the hospital at 75% of charges for them. Hospitals may also include the patient's entire hospital stay in its Medicare cost report and recover indirect costs on those patients. Finally, NEOB will also pay appropriate Anesthesia and Surgeon charges for the organ recovery surgery.

Based on these discussions, CHB finance requested NEOB to review the last 3 BDD organ donors at CHB. This has provided the opportunity for CHB Finance to validate NEOB's coverage assertions and to determine that they are accurate.

The same principle of reimbursement for organ recovery charges of DCD organ donors would apply. Specifically, the costs of organ recovery after declaration of death has been made would be reimbursed. The support of the potential donor up until that time would be considered the same as for a non-donor and, as "end of life" support, would not be reimbursable. Any additional tests performed to determine the suitability of the donor would be reimbursable, as would any pre-mortem interventions directed to organ preservation and donation in a DCD context, if hospital policy were to allow them and, after family consent, clinicians were to order them. In the case of a "dry run" (*i.e.,* when a family approves donation but the potential donor does not die with sufficient circulation to permit survival of the organs), the NEOB would generally reimburse any donation-specific charges such as blood tests performed on the donor to define blood type, possible infections, etc. In general, OPOs have not reimbursed surgeons or anesthesiologists for "stand-by" charges in these situations, but this issue is being reconsidered on a national basis.

NEOB also agreed with CHB Finance to establish procedures for prompt identification of costs for which it will reimburse, so that CHB can submit any appropriate residual claims to commercial payers within their mandated timeframes. At the moment, of course, these

procedures will be limited to brain dead donors, but if Children's were to permit DCD, then those procedures would be extended to DCD as well.

NEOB is drafting a written statement of these principles for CHB Finance approval. We anticipate that statement would be finalized shortly.

Based on this discussion and assuming implementation by CHB Finance of those approved procedures, it was concluded that a DCD protocol would not result in any financial risk for either CHB or a donor family, and that specific procedures and tests will be reimbursed to the hospital at competitive rates.

4. SUMMARY OF PHASE 1 & FOUNDATIONS FOR PEDIATRIC DCD

In July 2005, a summary of the Phase I deliberations from the Task Force on Donation after Cardiac Death was presented to the Medical Staff Executive Committee (MSEC) at Children's Hospital Boston. This report stated that a protocol for DCD could be consistent with the mission of Children's Hospital, provided the following eight foundational criteria were met:

1. Each child will be an appropriate candidate for withdrawal of life support under circumstances not involving the prospect of organ donation.

2. The withdrawal of life support process will be consistent with established practices at CHB, and there will be no physical harm, suffering or hastening of death to the child by the DCD process / protocol. The withdrawal of life support will be conducted in a compassionate and sensitive fashion that respects and preserves the human dignity of the patient.

3. There will be rigorous oversight of protocol development and the subsequent implementation. Resources will be made available to ensure independent oversight and monitoring of the DCD process and outcomes, with controls and authority established to prevent conflicts of interest, variance from the established protocol, and violations of any of these eight foundational criteria.

4. CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but the implementation of the protocol will not alter the quality of care in the ICU or the trust of families that the welfare of their child is their and the staff's paramount concern. DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.

5. Participating families will give genuine informed consent that includes a statement that parents can change their mind at any time in the process. They will be informed of (i) the differences between the orchestration and experience of death, for both their child and themselves, if their child is going to be a DCD donor or not, and (ii) other facts likely to make a difference in their decision (*e.g.*, the likelihood of the organs going to another child).

6 The child will clearly be dead, which implies no potential for cognition before organ removal takes place, and our criteria for declaring death, including our concept of "irreversibility," will be ethically and medically justifiable.

7. Diversity in religious, cultural and personal values will be respected. Staff who object to DCD may avoid participation.

8. There will be no extra financial costs to the family from DCD participation.

Sixteen of the seventeen members of the Task Force supported this recommendation. The remaining member felt that the requirements of the procedure itself (the need to take steps that are not for the patient's direct benefit, the need to retrieve the organs within a fixed amount of time and the limitations placed on parental contact) compromises the human dignity of the

patient and therefore causes harm; however, this member determined that these reservations, based on personal spiritual beliefs and values, should not prevent the Task Force as a whole from proceeding as outlined here.

In all areas of clinical care and research, children are identified as a unique and vulnerable population, in need of special protections and safeguards. Policies and procedures developed for the care of adults frequently require modification before they can be adapted for use in children. The Task Force recommended that these considerations should guide the process of adopting aspects of existing protocols into an approach to be used at Children's.

Motion presented to the Medical Staff Executive Committee:

"That MSEC approve the Phase I Report & Recommendation of the Task Force on Donation after Cardiac Death, and support the protocol-development proposed by the Task Force for its second phase, with the understanding and intent that a DCD protocol should be adopted at CHB only if it meets the conditions established by the Task Force."

Passed unanimously by MSEC 7-12/2005

Section III

PHASE II

1. WORK PLAN
2. SUBCOMMITTEE REPORTS
   - 2.1 PROTOCOL FOR ORGAN DONATION AFTER CARDIAC DEATH
   - 2.2 TIME OF DEATH
   - 2.3 FAMILY VIEWS & ETHICS OF PROXY CONSENT
   - 2.4 INFORMED CONSENT
3. CONSENSUS PROCESS CONCLUDING PHASE II

Section III

PHASE II

1. WORK PLAN

The work plan for Phase II of the Task Force centered around development of the protocol, based on the 8 Foundations established in Phase I. Aspects of the protocol and implementation were addressed by four subcommittees.

PROTOCOL DESIGN:

Questions: *Can we meet the 8 conditions set in the Phase I report? What is the best possible DCD protocol we could offer here at CHB?*

The subcommittee, which included Task Force members, additional ICU & OR staff, and a NEOB representative, developed a detailed protocol which was debated with Task Force and revised in several iterations December 2005 – March 2006.

TIME OF DEATH:

Questions: *If death must be declared and organ harvesting proceed beginning at 2-5 minutes after acirculation, can we be sure children have no possible awareness or negative near-death experience at that time? As between 2 and 5 minutes, how long should we wait?*

The subcommittee, including Task Force members and a CHB neurologist reviewed US and EU scientific literature and prepared report supporting a 5 minute waiting period. Presented and discussed with Task Force November 2005.

FAMILY VIEWS & ETHICS OF PROXY CONSENT:

Question*: If parents want DCD, can it be ethical for us to accept their choice even though it cannot be said to be in their child's best interests?*

The subcommittee reviewed ethics literature and actual practice at CHB regarding exceptions and alternatives to the best interest standard, met with ethics committee members and prepared a report suggesting rationale whereby DCD could justifiably be seen as an ethical choice by parents. Their report and findings were discussed with Task Force December 2005.

INFORMED CONSENT:

Question*: What kinds of information would parents need to have? Who should provide it and when?*

The subcommittee developed detailed guidelines for informed consent, which were discussed with Task Force February 2006.

2. SUBCOMMITTEE REPORTS

2.1 PROTOCOL FOR ORGAN DONATION AFTER CARDIAC DEATH

The enclosed protocol was developed by the Protocol Design Group of the DCD Task Force, comprising: Peter Laussen (Chair), Dorothy Beke (CICU nursing), Jackie Berlandi (OR nursing), Jeffrey Burns (Chief, Critical Care), Nancy Craig (Respiratory Therapy), Bill Harmon (Nephrology), HB Kim (Director, Pediatric Transplant Center), Kevin O'Connor (NEOB), Lisa Pixley (MSICU nursing).

The Protocol was discussed, debated, dissected and refined at several Task Force meetings, until most of the Task Force was satisfied the Protocol met the 8 Foundations for pediatric DCD.

The protocol was developed to provide for kidney DCD, and the Task Force's recommendations are limited to kidney donation. However, DCD is an evolving field, and during the course of deliberations, the Task Force became aware that pediatric liver DCD may become feasible in the future. If CHB wishes to consider DCD for livers or other organs in the future, careful consideration should be given to the medical and ethical implications of each. For example, the minimum age and other medical criteria for liver donors may be different than for kidney donors. Also, from an ethical perspective, liver donation could present a greater likelihood of conflicts of interest for ICU staff. Although prospective kidney recipients at CHB are usually being cared for at home or on a nephrology unit just prior to identification of a donor, the prospective recipient of a liver may be a patient on the same unit (especially the Medical Surgical ICU) at the same time as the prospective donor.

The protocol is not meant to be a final or rigid document. Rather, it represents a considered process by which DCD could occur at CHB, consistent with the foundational criteria established by consensus of the Task Force. In the discussion below, we outline considerations that the Task Force recommends to guide the planning process that would be necessary if a decision to implement the protocol is made. Following that discussion is the text of the protocol.

CONSIDERATIONS FOR IMPLEMENTATION OF THE DCD PROTOCOL

If CHB leadership should decide to move forward with the protocol, there remain important concerns that would need to be addressed during the implementation phase. These include the following.

1. The withdrawal of life support is an emotionally charged time for families and staff. While the protocol clearly states that the decisions and customary processes for withdrawal of life support used at CHB over many years should not be altered in any way by adopting a DCD protocol, and that the decision for withdrawal of life support should ideally occur before discussing DCD, there are real concerns for protecting the integrity of this process by separating it from the process of organ preservation and donation. To

this end, implementation planning should address the most effective ways to ensure the following:

a. Staff must be confident that the withdrawal of life support is an ethically justifiable decision for the patient and family, as is always expected at Children's Hospital.
b. A mechanism for immediate review and resolution of staff concerns during the DCD process should be available via access to senior staff or a specific DCD service authorized by MSEC to independently oversee the process. (See section below.)
c. Despite the absolute intent to keep WLS and DCD decisions separate, staff must be prepared to respond to families if they ask about donation before making a decision about withdrawal of life support. Staff need to be able to address family concerns while attempting to minimize the conflict of interest involved in considering both decisions at once. Specific training such as offered by the PERCS program may be useful to develop specific strategies for such conversations. The protocol limits pre-mortem interventions and ensures consistent practice from clinician to clinician and case to case.
d. At any time during the DCD process, the family will be able change their mind and DCD will be stopped.
e. The process for withdrawal of life support and proceeding with DCD must not be rushed. Throughout the process, the usual and customary family supports will be available.
f. As is usual practice at Children's Hospital, an ethics consult may be called whenever staff or family members are concerned about the ethics of the decision to withdraw life support or donate organs, the integrity of the process, conflicts of interest, or unacceptable alterations in the care of a patient prior to or during withdrawal of life support. Since time will be limited, implementation planners should work with the Ethics Advisory Committee to facilitate this process for DCD-related consult requests.

2. Independent oversight is essential to the integrity, credibility and success of the DCD process. The Task Force considered the following possible means for oversight, which could be refined during the implementation phase:

a. A senior clinician or clinicians to be appointed by the Medical Staff Executive Committee to oversee the integrity of the process and ensure that the protocol is followed, address possible conflicts of interest in the decision making and management of patients and ensure the process for withdrawal of life support is separate from that of organ procurement. For DCD patients from the MSICU, the CICU director or designee will oversee the process, and for DCD patients from the CICU, the MSICU director or designee will oversee the process.
b. A separate *DCD Service* at CHB to be contacted once consent for donation has been agreed upon. Potential roles would include helping coordinate and/or oversee the withdrawal of life support and DCD with staff at CHB and NEOB, collecting prospective data on the withdrawal of life support for quality assurance, including

the reactions of parents to DCD. The chairperson of the DCD Service should be appointed by the MSEC.

3. The question as to whether DCD should be offered to the families of all patients considered to be potential candidates for DCD, or reserved only for families who specifically request organ or tissue donation ("don't ask, do tell" approach), is a difficult one. Because of the unique issues surrounding withdrawal of life support and DCD for pediatric patients and families, there is concern that family trust in Hospital staff may be adversely affected by request for DCD from staff in the context of WLS. Also, staff members may be more comfortable participating if the parents' desire for donation is perceived as deep or long-standing enough for them to raise the question themselves, minimizing the possibility of a decision to donate based on unintended pressure from staff or NEOB. Reserving DCD for families who ask first also can reduce the involvement of staff and NEOB in evaluating every patient as a possible DCD candidate, an intrusion into patient care that some Task Force members regard as disproportionate to the benefits offered by DCD.

On the other hand, there are arguments that "don't ask/do tell" is unfair to CHB families. Failure to ask a family about donation may preclude their obtaining the comfort that solid organ donation can offer (tissue donation will still be offered) and may turn out to have a disproportionate effect on families who are less educated and consequently less aware of donation as an option. Ordinarily, if a procedure is offered to any patients at CHB, it should be offered to all for whom it is appropriate, on an even-handed basis.

The Task Force concluded that, if DCD is offered here, a "don't ask/do tell" policy would not be appropriate. In addition, it was noted that there is very limited research on family attitudes toward DCD and experiences surrounding donation. To the extent consistent with compassionate care for our families, research should be conducted to guide future decision-making about DCD.

4. It is expected that some staff will have moral objections to DCD and be uncomfortable with taking part in the DCD protocol. In order to protect both staff and patients,

a. Staff must be able to choose not to take part in DCD, without fear of pressure from colleagues or reprisals from supervisors.
b. Consistent with CHB policy to honor staff consciences while maintaining the quality of patient and family care, staff should be provided with education regarding DCD and an opportunity to opt out well in advance of any implementation, so that appropriate staffing can be planned. For clinical and support services with a small number of members, careful consideration must be given to ways to make this possible. If opting out is not feasible on some services where staff members object to participation, foundational criterion #7 cannot be met.
c. A confidential staff survey should be conducted, and a review process established to track all aspects of DCD, including staff reactions for both positive and negative feedback, as described below.

5. Careful staff training and education must be conducted before the implementation of any protocol.

6. A thorough debriefing, review and report should be undertaken after each DCD case. This includes:

a. Review at unit specific M&M and Bereavement Council meetings. Bereavement review to include both immediate and extended follow-up with families. Later, in the event that DCD is offered to families who have not requested it, data should be collected regarding the concerns and experiences of families who decline to donate. Any research must be consistent with compassionate care and with IRB approval.
b. Review by the Operating Room and Intensive Care Governance Committees. Reports from each of the above to be forwarded to the Co-Chairs of the Task Force, who will in turn forward them to the CEO, the Vice President for Patient Care Services, and MSEC.
c. An independent review of the protocol, implementation and outcomes to be undertaken, preferably by the reconvened Task Force, after the first 2 DCD cases or after 12 months, whichever comes first. This review should be reported to the CEO, the Vice President for Patient Care Services, and MSEC. A decision should then be made whether to continue or modify the DCD program.

DCD PROTOCOL[o]

1. DECISION TO WITHDRAW LIFE SUPPORT:

The decision to withdraw life support for any patient will be made jointly by the intensive care staff and the patient's family, according to the clinical condition of the patient and the family's wishes. There will be no change to the current process and practices by which these decisions are made. The discussion and/or subsequent consent to proceed with DCD is a separate process, independent to and made after the decision to withdraw life support.

2. OFFER FOR DCD:

2.1 This protocol outlines the process to be followed with the intent to approach all families of patients who may fulfill criteria for DCD. For each dying child who might be a candidate for DCD, the ICU attending will assess whether there are any absolute contraindications to DCD.

Absolute clinical contraindications to DCD:
Confirmed HIV sero-positivity or diagnosis of AIDS
Active malignancy, excluding primary brain tumor.
Encephalopathy of unknown etiology
Relative contraindications to DCD:
Active sepsis.

2.2 Prior to approaching a family to discuss the process of withdrawal of life support, and when there are no absolute contraindications to DCD, the ICU attending will contact the NEOB to discuss pre-screening criteria for DCD. This can be done via telephone. Prescreening criteria are to be formulated by the transplant services at CHB and the NEOB, and will include:

Organ specific criteria (organ viability)
Likelihood that the child will die within I hour after WLS
Likely availability of a suitable recipient (families will not be approached for DCD if there is no recipient based on patient age or size)[p]

2.3 Following the discussions about the process of the withdrawal of life support with the patient's family, the ICU staff will offer the possibility of organ donation for those patients who meet the prescreening criteria. This may be done at a separate discussion with the family and does not need to be an in-depth discussion about DCD, but sufficient to gauge whether the family may be interested in DCD and initiate NEOB involvement.

---

[o] See schematic flow diagrams p. 70-72.

[p] If warranted by the data on acceptance of young children's organs, minimum age criteria may be established as a contraindication for DCD.

2.4 Training for staff should be developed to facilitate this conversation in a sensitive and respectful manner.

2.5 NEOB will be contacted for detailed patient assessment after families have decided to consider or proceed with donation, or if they request further discussion and information to determine feasibility.

3. EVALUATION FOR DCD:

3.1 The primary contacts for CHB will be notified at NEOB. To facilitate interactions between the NEOB and intensive care staff, the NEOB will assign certain staff to primarily work with Children's Hospital when organizing DCD. The intent is to limit the number of contacts and to establish consistent lines of communication.

There will be a collaborative assessment by ICU and NEOB staff as to suitability of the patient for DCD. This will involve chart review, a review of clinical state, and likelihood the patient will have cardiac death within 60 minutes of withdrawing life support.

3.2 Once it has been determined that the patient fulfills the criteria for DCD based on clinical assessment, chart review and evaluation of existing laboratory data, the ICU staff and NEOB will jointly meet with the family to discuss DCD, and if the family is interested, outline the DCD process and how this would affect the withdrawal of life support. The discussion will be guided by the informed consent guidelines specified in Appendix A.

An estimate of the time frame for DCD will be conveyed to the patient's family and ICU staff. The time frame for coordinating DCD is usually estimated to be 6 to 8 hours. If the time frame is too prolonged for the family, they may opt out from DCD. The process will not be rushed, and families may request to prolong the time frame to allow for other family members to be present.

3.3 If the family decides to proceed with DCD, consent from the family will be documented by the intensive care staff together with selected NEOB staff.

3.4 Medical/social/behavioral history will be obtained by intensive care staff together with selected NEOB staff.

4. ARRANGEMENTS FOR DCD:

4.1 The NEOB will coordinate DCD, including contacting CHB transplant surgeons who will perform the organ procurement surgery, and contacting the OR charge nurse and anesthesia staff to determine the availability of operating rooms and staffing for DCD.

4.2 There will be no pre-mortem interventions prior to or during the withdrawal of life support and extubation in the operating room that may hasten death or cause harm to the patient. Specifically this includes the pre-mortem placement of vascular catheters that would be used for exsanguination and infusion of cold preservative solution after death has been confirmed.

4.3 Intensive care staff will continue to manage the patient prior to withdrawal of life support and organ procurement, ensuring complete analgesia and comfort for the patient. The NEOB and transplant surgeons will not be involved or alter patient management. Possible changes in care due to DCD will be discussed in general with the family as part of the informed consent process.

4.3.1 Minor interventions prior to withdrawal of life support and organ procurement, such as fluid administration and adjustments to inspired oxygen concentration could be undertaken if the timing for DCD is delayed for logistical reasons or while waiting for family members to arrive prior to WLS. Minor interventions will be discussed with the family and be included in the informed consent signed by the parents or guardian.

4.3.2 If a major deterioration in the patient's condition occurs that would require an escalation of hemodynamic or ventilatory support to keep the patient alive and maintain organ viability, immediate consultation between the ICU staff, NEOB, transplant physicians and family must be undertaken before such escalation in treatment. There will be no major interventions or escalation to patient care solely for the purpose of organ preservation and that are not the direct benefit of the patient, including:

- *Persistent and ongoing fluid replacement, including transfusion of blood products,*
- *Change in mode of mechanical ventilation, i.e. introduction of high frequency oscillatory ventilation,*
- *Change or escalation to the pharmacologic support of the circulation , i.e introduction of new inotropic or vasoactive drugs,*
- *New drug administration, including inhaled nitric oxide,*
- *Mechanical support of the circulation (ECMO),*
- *Placement of new catheters or lines for vascular access or monitoring purposes.*
- *Cardiopulmonary resuscitation*.

4.4 A senior clinician or clinicians will be appointed by the Medical Staff Executive Committee to oversee the integrity of the process, address possible conflicts of interest in the decision making and management of patients, and take the role of an ombudsperson. This role may be performed by the MSICU and CICU directors. For DCD patients from the MSICU, the CICU director or designee will oversee the process, and for DCD patients from the CICU, the MSICU director or designee will oversee the process. The ICU directors will be charged with ensuring that the protocol is followed, that there is no coercion, and that the preparation and process for withdrawal of life support is separate from that of organ procurement. As the DCD

program develops and with experience, other medical or nursing staff may be appointed to fulfill this role. It may be desirable to develop a dedicated *DCD Service* to oversee the implementation of the protocol between CHB and NEOB staff. This service could also be responsible for prospectively tracking staff reactions and collecting data about the withdrawal of life support and parent reactions to DCD.

5. FAMILY PREPARATION FOR DCD:

5.1 Family will have complete explanations of what to expect in the ICU and OR and options will be given to family at that time (and throughout process). Specifically:

5.1.1 If acirculation does not occur within one hour after withdrawal of support in the OR, the patient will no longer be considered a donor, and the child will be brought back to a private room and whenever possible the same ICU room and comfort care continued. Tissue donation may remain an option.

5.1.2 The need to proceed with organ procurement after 5 minutes of acirculation will have been discussed and emphasized with the family as a requirement for successful DCD prior to the patient being brought to the OR.

5.2 ICU Charge RN dedicates room to that patient until hears from ICU RN that family has returned home (post-procurement),

5.3 ICU Charge nurse dedicates an ICU RN to the family until the family has returned home. On going support to the donor family provided in collaboration with NEOB staff.

5.4 O.R. RN will come to ICU and meet the family, and assist in transferring patient and family to OR. This RN is in addition to the perioperative staff preparing the OR for DCD.

5.5 ICU RN will offer and make child's hand/footprints and molds and offer lock of hair to family before going to O.R.,

5.6 No new access will be started on patient (a-line, CVL) once family has decided to re-direct care.

6. OPERATING ROOM:

6.1 The NEOB & transplant surgeons, OR nursing & anesthesia staff will determine time line for DCD and availability of ORs. Time frame to be communicated with family by either NEOB or ICU staff (may be 6-8 hours).

6.2 O.R. staff/anesthesia will make available 2 adjacent OR rooms, one to be utilized as an ante-room (OR A), the other where procurement (OR P) will take place.

6.3 The patient will be brought down to O.R. with the ICU staff (RN, ICU fellow and/ or attending), designated O.R. nurse, NEOB staff and family (if they choose to accompany their child).

6.4 In anteroom (OR A), the family has option of holding their child during extubation (as they would in the ICU room under usual circumstances). The child will be extubated in anteroom with family present.

6.5 Music, prayer, religious rituals, will be offered, available, enabled, and facilitated in OR anteroom to make every accommodation which would have been made in the ICU room. Anointing may be done in anteroom or in ICU room before transfer to O.R. Baptisms will likely occur in ICU room.

6.6 Heparin will be administered after withdrawal of life support and when acirculation is imminent:

-Older than 10 years: mean BP < 50 mmHg
-1 to 10 years: mean BP < 40 mmHg
- < 1 year: mean BP < 30 mmHg

6.7. The ICU attending or fellow declares acirculation within 1 hour of extubation. Physicians who are part of the transplant team, or who will be responsible for the care of the recipient, will not be involved. The loss of myocardial contraction and systemic perfusion, or acirculation, generally will occur before the loss of electrical (ECG) activity. Acirculation can be established by:

6.7.1 Palpation of pulses and auscultation of heart sounds, in combination with
6.7.2 Loss of ejection and pulsatility on the patient's arterial line if in place prior to withdrawal of life support, or
6.7.3 Absence of myocardial contraction and ejection by echocardiography.

NB: The loss of mechanical activity of the heart (*i.e.* ejection) often precedes the loss of electrical activity on the electrocardiogram; declaration of cardiac death is therefore not dependent on absence of ECG activity.

6.8 Once the heart has stopped the physiologic monitor will be turned off.

6.9 If the patient does not die within the 1 hour time period, he/she will be transported back to their ICU room.

7. ACIRCULATION:

7.1 Once acirculation has been confirmed, a 5 minute waiting period will be implemented to assure no auto-resuscitation of the circulation occurs. Unless there is auto-resuscitation, death will be declared at the end of the 5 minutes. During this 5 minute waiting period:

Parents and family will complete their final goodbyes in OR "A" at the time acirculation is declared.

The body will be placed on an OR table or stretcher and taken into the adjacent O.R. room (OR P), and be prepped and draped for organ procurement.

After being moved into OR P, either the arterial line wave form will be reviewed or an echocardiogram will be performed after 5minutes of acirculation to make sure auto-resuscitation has not occurred.

If there has been no auto-resuscitation after 5 minutes, and this is confirmed by the ICU physician, death will be declared and organ procurement can begin.

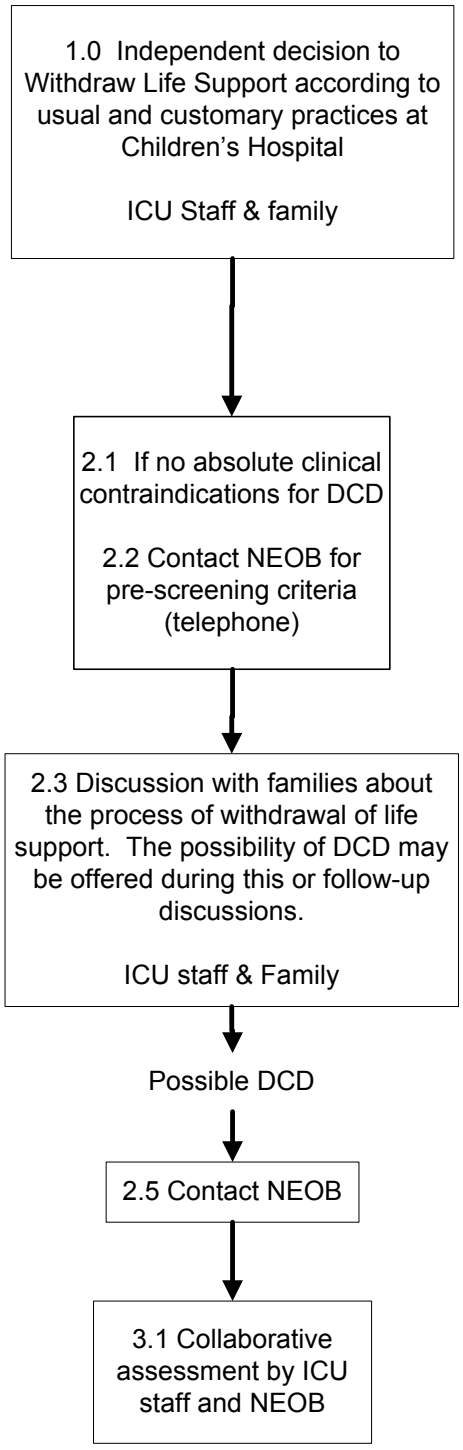
Parents may wait in OR A until absence of auto-resuscitation has been confirmed, and during procurement may wait in either child's ICU room, chapel, or a single private waiting room adjacent to the OR if they wish, or they may choose to go home.

If family wishes to see the child again after organs are procured, they may do so in the chapel (if available) or the ICU room.

7.2 In the remote chance that auto-resuscitation of the heart occurs, DCD will be cancelled and the patient returned to their ICU room.

8. ORGAN PROCUREMENT AND ALLOCATION

Per protocol as determined by transplant surgeons, NEOB and OR nursing.



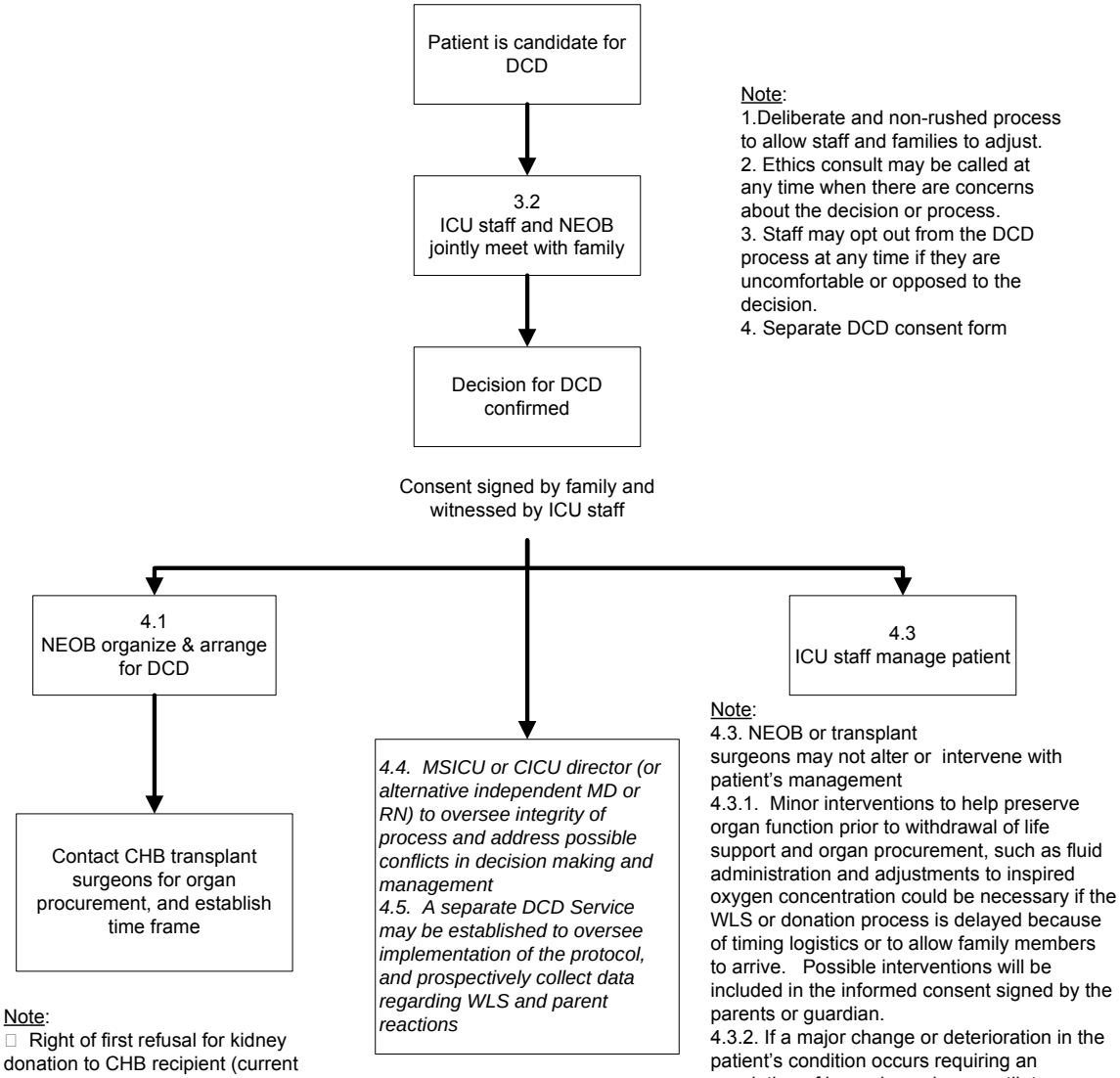
Note:
2.1. Will initially start with families who request or enquire about organ donation until DCD process established. Once the DCD process is established at CHB, ICU staff will discuss possible DCD patients (who do not have absolute contraindications), with NEOB prior to meeting with a family to discuss withdrawal of support. The intent will be to approach all families of patients who are possible DCD candidates based on clinical criteria.

Note:
2.1 Absolute clinical contraindications to DCD:
- Confirmed HIV sero-positivity or diagnosis of AIDS
- Active malignancy, excluding primary brain tumor.
- Encephalopathy of unknown etiology

Relative contraindications to DCD:
- Active sepsis.

2.2 Prescreening criteria include:
- Organ specific criteria (organ viability)
- Response to treatment prior to WLS (likely to die within I hour after WLS)
- Likely availability of a suitable recipient (families will not be approached for DCD if there is no recipient based on patient age or size)

Note:
3.1. NEOB will designate primary contacts to work with CHB. An ongoing cooperation and collaboration between ICU staff at CHB and NEOB is essential to facilitate DCD. The NEOB acknowledges the unique differences in the withdrawal of life support for children and their families and respects the autonomy of staff at CHB to facilitate and manage this process. In turn, staff at CHB acknowledge the importance of honoring the request by a family for organ donation.

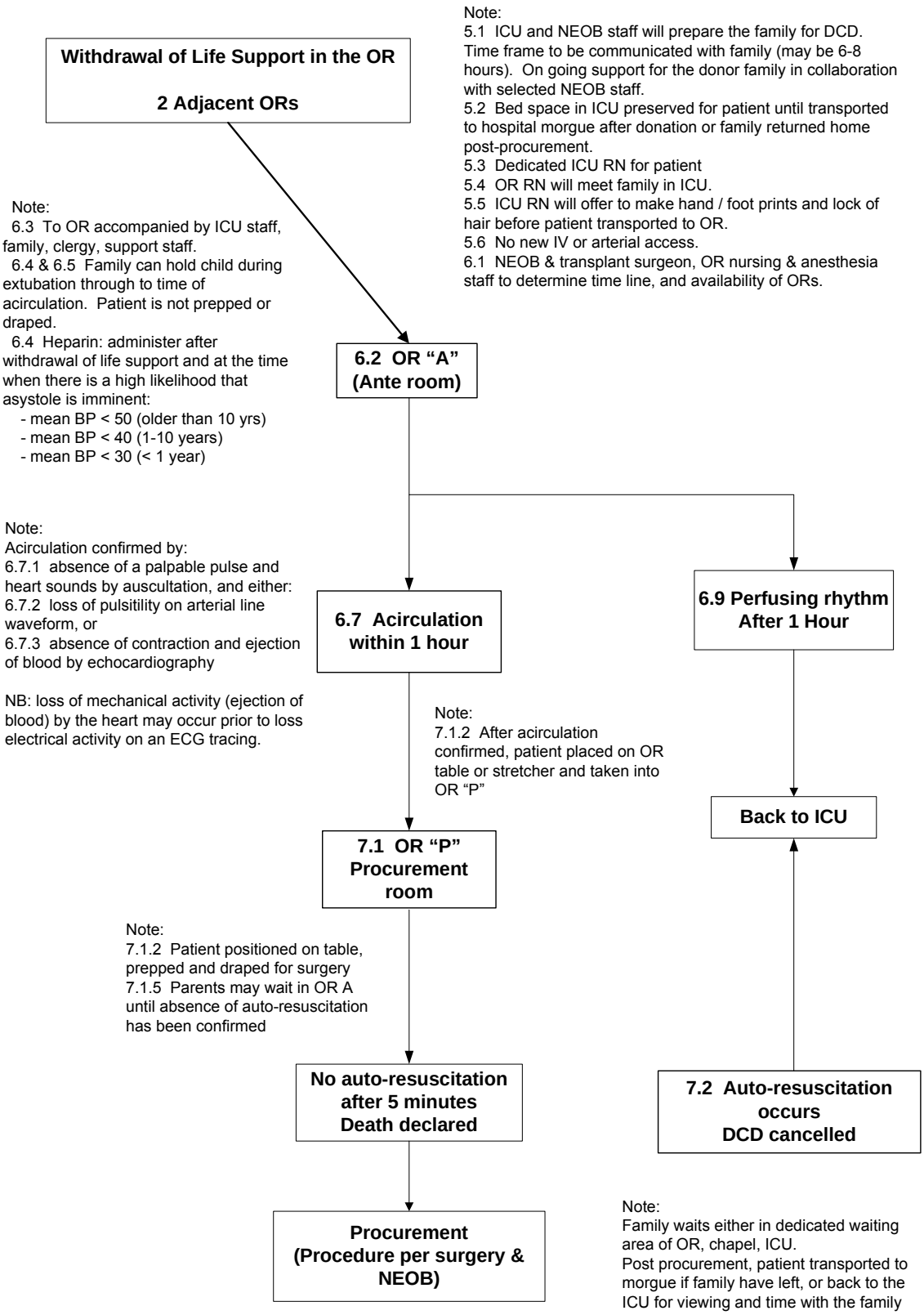


Note:
1.Deliberate and non-rushed process to allow staff and families to adjust.
2. Ethics consult may be called at any time when there are concerns about the decision or process.
3. Staff may opt out from the DCD process at any time if they are uncomfortable or opposed to the decision.
4. Separate DCD consent form

Note:
 Right of first refusal for kidney donation to CHB recipient (current allocation method, but likely to change. Other organs allocated according to existing protocols for brain dead organ donation)

4.2 No pre-mortem interventions that harm the patient or hasten death.

Note:
4.3. NEOB or transplant surgeons may not alter or intervene with patient's management
4.3.1. Minor interventions to help preserve organ function prior to withdrawal of life support and organ procurement, such as fluid administration and adjustments to inspired oxygen concentration could be necessary if the WLS or donation process is delayed because of timing logistics or to allow family members to arrive. Possible interventions will be included in the informed consent signed by the parents or guardian.
4.3.2. If a major change or deterioration in the patient's condition occurs requiring an escalation of hemodynamic or ventilatory support to keep the patient alive and maintain organ viability, immediate consultation between the ICU, NEOB, and transplant staff and family must be undertaken before such escalation in treatment. There will be no major interventions or escalation to patient care including:
-Persistent fluid replacement and transfusion of blood products,
-Change in mode of mechanical ventilation, i.e. introduction of high frequency oscillatory ventilation,
-Change or increase in pharmacologic support of the circulation , i.e introduction of new inotropic or vasoactive drugs
-ECMO
- New drug administration, including inhaled nitric oxide,
-Placement of new catheters or lines for access or monitoring purposes


Withdrawal of Life Support in the OR
2 Adjacent ORs
Note:
5.1 ICU and NEOB staff will prepare the family for DCD. Time frame to be communicated with family (may be 6-8 hours). On going support for the donor family in collaboration with selected NEOB staff.
5.2 Bed space in ICU preserved for patient until transported to hospital morgue after donation or family returned home post-procurement.
5.3 Dedicated ICU RN for patient
5.4 OR RN will meet family in ICU.
5.5 ICU RN will offer to make hand / foot prints and lock of hair before patient transported to OR.
5.6 No new IV or arterial access.
6.1 NEOB & transplant surgeon, OR nursing & anesthesia staff to determine time line, and availability of ORs.
Note:
6.3 To OR accompanied by ICU staff, family, clergy, support staff.
6.4 & 6.5 Family can hold child during extubation through to time of acirculation. Patient is not prepped or draped.
6.4 Heparin: administer after withdrawal of life support and at the time when there is a high likelihood that asystole is imminent:
- mean BP < 50 (older than 10 yrs)
- mean BP < 40 (1-10 years)
- mean BP < 30 (< 1 year)
6.2 OR "A" (Ante room)
Note:
Acirculation confirmed by:
6.7.1 absence of a palpable pulse and heart sounds by auscultation, and either:
6.7.2 loss of pulsitility on arterial line waveform, or
6.7.3 absence of contraction and ejection of blood by echocardiography
NB: loss of mechanical activity (ejection of blood) by the heart may occur prior to loss electrical activity on an ECG tracing.
6.7 Acirculation within 1 hour
6.9 Perfusing rhythm After 1 Hour
Note:
7.1.2 After acirculation confirmed, patient placed on OR table or stretcher and taken into OR "P"
Back to ICU
7.1 OR "P" Procurement room
Note:
7.1.2 Patient positioned on table, prepped and draped for surgery
7.1.5 Parents may wait in OR A until absence of auto-resuscitation has been confirmed
No auto-resuscitation after 5 minutes Death declared
7.2 Auto-resuscitation occurs DCD cancelled
Procurement (Procedure per surgery & NEOB)
Note:
Family waits either in dedicated waiting area of OR, chapel, ICU.
Post procurement, patient transported to morgue if family have left, or back to the ICU for viewing and time with the family

2.2 TIME OF DEATH

Committee: Tamara Vesel (Chair), Martha Curley, David Urion
Staff: Michelle Hogle

This subcommittee investigated the appropriate time interval from acirculation (defined as no ejection of blood from the ventricle and no systemic perfusion) to start of organ procurement. Specific questions included:

- After what period of acirculation is it logical to say that cardiac autoresuscitation is not likely to occur?
- After what period of no cerebral perfusion does the literature suggest that the physiologic events supporting cognition have ceased and are not likely to recover?
- After what period of no cerebral perfusion does the experience of pain cease?
- What is the basis of these statements, that is, how analogous are the situations to donation after cardiac death? What are the limitations of the information from this literature?

Current Practice with Children at the End of Life

At present, most children who die in intensive care unit settings after a decision has been made to forego life-sustaining treatment appear to do so with doses of sedatives and/or analgesics that have been increased at the time of this decision compared to the immediately preceding periods. The clinicians involved in these decisions appear to argue for these dosage increases based upon patient-centered concerns; hastening death appears to be an unintended consequence of this treatment decision. Thus, concerns regarding pain in children at the end of life seems central to most clinician's decision-making. This forms the backdrop for any discussion regarding treatment parameters in donation after cardiac death. The current practice of comfort medication administration at end of life should not be altered.

Time of Death

Reviewing the literature, the only logical time to set "time of death" in the setting of donation after cardiac death would be acirculation ("no-flow state").

Autoresuscitation

Autoresuscitation does not appear to occur after two minutes of acirculation. An analysis of 112 reported cases, described in 7 studies across a 58-year period, showed that autoresuscitation occurred only in 2 patients after sixty-five seconds. Those two patients did not meet the criteria of cardiac arrest.

Cessation of Cognition after Cardiac Arrest

The literature regarding this dates back to the 1940's. Review of sixty years of studies suggest that the physiologic findings which are consistent with cognition cease within a very short time after a no-flow state occurs; after five minutes of no-flow at normal body temperatures, cognitive recovery appears unprecedented. This is based on studies utilizing

conventional electroencephalography, electrocorticography, and bispectral index monitoring in clinical as well as experimental settings. Bispectual index monitoring was used to describe the level of awareness in 12 palliative care patients from the onset of unconsciousness to death. When the patients were unconscious their BIS was 54±12 (equivalent to hypnosis found in general anesthesia). Immediately before death the BIS dropped to 44±10. At the time of death the BIS plunged from 44 to 0 often after an equally dramatic rise.

Pain

Review of the literature suggest that the central nervous system structures which mediate pain appear to be irreparably injured after five minutes of no-flow state, and in all likelihood some time before this. This fact is coupled with an above stated fact that patients lose consciousness after acirculation in a matter of seconds not minutes. This means that central processing of pain is already interrupted before the structures of the central nervous system that mediate pain are irreversibly damaged. This information is further buttressed by a review of the near death experience literature. Survivors of near death experiences, both pediatric and adult, uniformly report that the only painful experiences they report are the resuscitative efforts which brought them back to normal cardiac function and cerebral recovery. The events before this are not reported as painful, suggesting that the disruption of body image reported as a part of the core experience is associated with some protection from physical pain.

Limitations of this Review

These conclusions are inferences which come from studies which have examined the neurophysiologic correlates of no perfusion due to experimental or accidental cardiac arrest, as well as survivors of near-death experiences. The physiology of these situations is likely to correlate closely with what would transpire in donation after cardiac death. The scenarios reported in patients who survive near-death experiences suggest that low-flow states can be associated with a prolongation of some form of consciousness, but there does not appear to be evidence for the prolongation of consciousness or the ability to experience pain after five minutes of no-flow state.

Recommendation:

In the setting of normothermia, the patient may be prepared for organ donation after *5 minutes* of uninterrupted acirculation.

References

1. Burns JM, Mitchell C, Outwater KM, Geller M, Griffith JL, Todres ID, Truog RD. End-of-life care in the pediatric intensive care unit after the forgoing of life-sustaining treatment. Crit Care Med 2000; 28(8):3060-6.

2. DuBois J. Non-heart-beating organ donation: a defense of the required determination of death. J Law Med Ethics 1999; 27(2):126-36.

3. Barbato M. Bispectral index monitoring in unconscious palliative care patients. J Palliat Care 2001; 27(2):102-8.

4. Deogaonkar A, Gupta R, DeGeorgia M, Sabharwal V, Gopakumaran B, Schubert A, Provencio JJ. Bispectral index monitoring correlates with sedation scales in brain-injured patients. Crit Care Med 2004; 32(12):2403-6.

5. van Lommel P, van Wees R, Meyers V, Elfferich I. Near-death experience in survivors of cardiac arrest: a prospective study in the Netherlands. Lance 2001;358(9298):2039-45.

2.3 FAMILY VIEWS AND ETHICS OF PROXY CONSENT

Committee members: Patti Kraft (Chair), Meg Comeau, David Coulter, Charlotte Harrison, Roberta Hoffman, Mary Robinson
Staff: Michelle Hogle

At the conclusion of Phase I, a primary motivation for pursuing a DCD protocol at CHB was the Task Force's view that some families would derive significantly more solace from this option than from other options available to them (donation of other tissues, other types of memorialization, etc.). We thus began Phase II with the hypotheses that families who choose DCD will derive a significant benefit—solace—and that this is a benefit worth pursuing. It became apparent, however, that we first needed to address how parent/family interests should be weighed against the child's interests. The most familiar "best interest of the child" standard seemed difficult to meaningfully apply to most DCD candidates. In Phase II, our subcommittee thus considered and presented two issues: (1) is it ethical to permit parents to choose DCD for their child, and if so, (2) can we determine whether families would in fact derive significant benefit from DCD?

Our conclusion with respect to (1) is that the DCD decision could be ethical if certain conditions are met. Although the "best interest" standard does not meaningfully apply, other ethical frameworks could permit parents to make such a decision even though it does not directly benefit their child. Certain conditions would have to be met to ensure that the decision, and process, would be ethical. These conditions and the ethical frameworks considered are described more fully in our subcommittee report, which is found in Appendix G.

With respect to (2), we concluded that whether families would in fact derive solace from DCD is an assumption that cannot be meaningfully tested. but is one that we are comfortable making, at least for present purposes, even absent hard data. The rationale for this conclusion, and for our decision not to survey parents in Phase II, is set forth below.

One primary difficulty with a survey to determine if DCD would benefit families is the choice of who to interview: Parents who have donated their child's organs? Parents who were approached but chose not to donate? Parents who could have donated through DCD but it was not offered? Parents with terminally ill children? People "off the street"? Furthermore, the only survey structure that could provide meaningful results would be focus groups: DCD would have to be described in detail and compared to the "standard" way of treating and memorializing a dying child before informed opinions could be solicited. Focus groups would yield a small number of non-generalizable, anecdotal responses. What would our criteria be—if a certain number of respondents said "no" or "yes" to DCD, would that determine our course of action? We concluded that the effort involved and the anecdotal responses that would result would be better utilized in evaluating an actual draft protocol and informing the structure of CHB's protocol and implementation.

Notwithstanding the difficulties of demonstrating solace, we are comfortable assuming solace for families who choose DCD, until multi-center, generalizable research can be done. Solace is a perceived benefit: if parents choose DCD, it must provide a benefit for them. Parents are the

best, and indeed the only, judges of this benefit. This assumption respects the parents' autonomy and right to choose an option that they perceive to benefit their family.

In reaching our conclusions, we considered the effects that participation in DCD might have on the donor children and their families. Factors we identified are summarized in the following table.

POSSIBLE EFFECTS OF DCD ON CHILD AND FAMILY

HARMS TO /BURDENS ON CHILD	**BENEFITS TO /INTERESTS OF CHILD**

- would the child really want to die this way?
 	
- loss of dignity: being treated as a "vessel for organs" not as a dying child; receiving non-therapeutic "Rx" (even if not physiologically or psychologically harmful)
 	
- hastening of death
  - Protocol design problem: protocol elements (that per se could hasten death or set criteria for declaring death at premature point
  - QC problem: de facto hastening of declaration of death resulting from rushing to meet protocol requirements or OR schedule; timing of actual declaration of death driven by organ survival time rather than documented loss of function
 	
- use of invasive pre-mortem procedures:
  - pain, discomfort
  - need for sedation which would lead to loss of awareness/communication
 	
- physical separation from family at time of death (unable to be held)
 	
- suffering from awareness of separation or awareness of other conditions of dying that are different from our usual "good death" (OR setting)
 	
- any possible level of consciousness/awareness after death is declared, requiring sedation for purpose of taking organs
 	
- experience of "ensouled" person (in some traditions, still embodied spiritually even after physiological criteria for death are met); neglect of spiritual interests of child; negation of spiritual experience of the process of death
	- fulfillment of own desire to be an organ donor, in the case of a mature minor who has indicated this desire on driver's license or donor card (but would this person want to donate in the conditions necessary to DCD?)
	
	- comfort in believing that family will derive solace from donation/"living on" (hard to attribute to younger children)
	
	- altruism toward unknown recipients or society (hard to attribute to younger children)

HARMS TO FAMILY	**BENEFITS TO FAMILY**

- harms from participation in procedure itself:
  - physical separation from child
  - witnessing bedside preparation
 	
- harms from offer of DCD & I/C discussion:
  - distress from being confronted with/hearing about process
  - disrespect or distraction of being asked to think about DCD during dying time, rather than treating that time as a gift; in some traditions, it's disrespectful to talk about death or make funeral arrangements while person is dying
 	
- harms from having to decide quickly at emotional time with imperfect information:
  - risk of making "wrong" decision (by own stable values) because DCD is too complex to process fully, cognitively or emotionally, when child is dying
 	
  - feeling uncertain that child would have wanted this or that it was the right thing to do; worry that they didn't provide dignity
 	
  - regret/more grief if the donation isn't successful: child doesn't die soon enough, organs aren't usable
	- autonomy:
	  - opportunity to know about and choose from full range of possible options for meaning and solace at their child's death
	
	- solace:
	  - belief that child can "live on" in a more meaningful way through solid organ donation than through other means (tissue donation, pursuing child's projects, other forms of memorializing the child)
	  - belief that they are enhancing meaning of death/death not in vain/some good will come, more than possible through other means (see above)
	
	- fidelity:
	  - belief that they are fulfilling child's wish to be organ donor (if clearly indicated)
	
	- altruism, toward
	  - organ recipients
	  - society

Our recommendation, independent of the findings of other subcommittees, is that it can be ethical to accept parents' choice of DCD for their child, even though it is not in the child's "best interests," as long as the protocol meets specified ethical requirements.

Acknowledgments: The subcommittee thanks the following individuals who consulted with us regarding the ethics of proxy consent: Steven Joffe, Judith Johnson, Christine Mitchell and David Waisel.

2.4 INFORMED CONSENT

Committee members: Adrienne Randolph (Chair), Dot Beke, Meg Comeau, Patti Kraft, Charlotte Harrison, Elaine Meyer, Mary Robinson, Patrick Taylor

Committee recommendations:

The process of obtaining informed consent for DCD should follow these guidelines:

A. It is consistent with the mission of Children's Hospital, Boston to ensure that consent is fully informed. This means that the risks, benefits and alternatives be discussed as well as any other relevant issues that may alter the family's willingness to consent. The NEOB form, based on limited legal requirements applicable to them (as explained by their counsel), is insufficient for this purpose. There should be an additional consent form specific to Children's Hospital, Boston.

B. The CHB consent form should include discussion of risks, benefits and alternatives using estimated probabilities when possible:

- That we distinguish between organ and tissue donation and that if they want to donate tissues, they can do so after death without altering the usual process of withdrawal of life support.
- That we clarify that the only organs that they can donate at the current time are the kidneys.
- That the family can change their mind any time during the process.
- An estimate of the probability of a failed attempt at donation. This could be because the organs are not usable or because the patient may not die within 60 minutes. The family should be told the risk that, if the patient does not die within 60 minutes, he or she will return to the ICU to continue the dying process.
- The very low probability that the organ would currently go to a pediatric recipient, and the low probability that it would go to a recipient who is a patient at CHB.
- The inability to return the organs to the body for burial or cremation if the organs are not able to be transplanted.
- The actual steps in the protocol. It should be clearly stated how participation in this protocol would change the care from what they would receive if they did not participate.
- That there may be minor variations in clinical management required that are done solely for the goal of organ preservation for the recipient
- That staffing may change because not all staff participate in the DCD process.
- That if they do not consent to the process, the alternative is our usual standard of care and that their care will not change if they decline participation.
- That usually the DCD process has no direct benefit for their child but may offer comfort to the family and does have direct benefit to the recipient.

C. There should be a separate team not involving the care team who go with NEOB to obtain consent. The process we suggest is that the attending MD introduce the NEOB and separate

team and then be available to the family afterwards for further questions. The reason for this is to minimize any pressure the family may feel to make a decision they believe is what the care team wants them to do. As in obtaining consent for research studies, it has been noted that families may try to please the caregivers or may be worried that their care would change if they decline participation. The MSICU currently does not allow the treating team to obtain consent for research studies. By having a separate team that is trained in the consent process, the family can make an objective decision with minimal pressure. Individuals eligible to participate on this consent team would include third year fellows, attendings, and senior nursing staff.

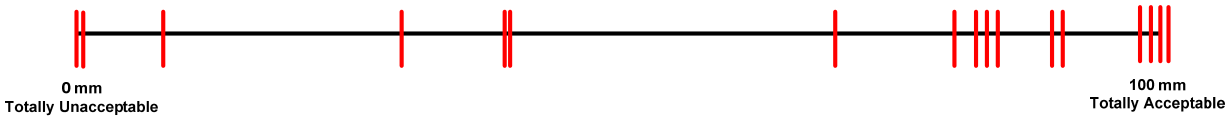
D. Prior to discussing DCD with the family, there should be a team meeting or "huddle" with NEOB to discuss the optimal approach to minimize any negative experiences for the family. NEOB should be introduced as independent of Children's Hospital, Boston and we should not give the impression that they are part of the institution. They should be introduced in neutral terms as representatives of the NEOB, here to discuss the possibility of organ donation.

3. CONSENSUS PROCESS CONCLUDING PHASE II

Preliminary Straw Poll

"Offering DCD on the terms of the protocol is acceptable to the mission of Children's Hospital."

At the completion of Phase II deliberations in March 2006, each Task Force member was to asked to indicate on a scaled line, 0 (totally unacceptable) to 100 mm (totally acceptable), his or her position as to whether the DCD protocol met the Mission of CHB and the 8 Foundations defined at the end of Phase I deliberations.



Specific comments by individual Task Force members

1. I believe the protocol is comprehensive and clinically sound. It is also thoughtful and compassionate from the perspective of families. However, since I don't believe DCD is consistent with the mission of the hospital, I cannot support this statement. (score 10 mm)

2. Only offer this to those who ask for it. AKA "don't ask, don't tell" (score 0 mm)

3. I don't think we are ready yet to implement the DCD protocol. The protocol as written is good, but the context for using it is not, and more work needs to be done first. I would be happy to meet with others to explore a common position statement if others want to do so (score 40 mm)

4. Continued discussion and clarity re staff training and ongoing staff support as this goes forward and is potentially implemented. Training-training-training (score 85 mm)

5. I think the protocol is excellent—my issues would involve staff acceptance and general medical acceptance of DCD (should CHB, as a pediatric institution, wait until DCD is more mainstream?) (score 70 mm)

6. To post case review as described in the proposed protocol (score 100 mm)

7. ICU and NEOB must work collaboratively. Candidacy for organ donation should not be denied to eligible families (score 100 mm)

8. Role of NEOB. Clear details of death confirmation (score 83 mm)

9. (i) For some families this will clearly be a good thing to offer and provide. (ii) For many families, the involvement of NEOB and the inherent conflicts of interest created by any DCD protocol will diminish the quality of the end-of-life care we provide. No changes in the protocol can entirely mitigate this inherent problem. (iii) Adrienne's data suggest that the number of organs procured in this way will be small. From the perspective of NEOB, the primary benefit of our adopting a DCD protocol will not be the organs obtained, but the public relations benefit of having our prestigious pediatric hospital "on board." For me, the cost/benefit analysis of this tilts in the direction of not adopting the protocol. I do recognize, however, that this will deny an important opportunity for a small number of families for whom this would be desirable. (score 30 mm)

10. My rating is quickly nearing 100. We hear concerns expressed of members that I fell have been addressed and protocol made clearer. It has been made clear that the Committee's aim now is to not seek unanimous endorsement but to address concerns expressed. Currently I cannot identify any adjustment needed in the protocol, but realize this is still hesitation from members. (score 90 mm)

11. illegible (score 81 mm)

12. (score 8 mm)

13. (score 91 mm)

14. (score 40 mm)

15. It appears from our discussions that we have not solved the problems regarding the relationship of CHB with the NEOB. We would need to show progress in this regard. Also, I see the need for very rigorous oversight with regards to 4.3.2. This is the slippery slope for me. (score 83)

16. (score 100 mm)

17. I am still concerned about the organ bank and its influence on physician autonomy and relationship with the patient and parents. I think that the most important at this point is an education of the staff in the hospital and I am not clear who is going to be in charge of it?! I found this process of last 1 ½ year fascinating, I learned a lot and that's why I am able to accept the protocol. I hope that similar process will occur with the staff. (score 95 mm)

FINAL CONSENSUS PROCESS

There was general agreement that the protocol designed by the Task Force is the best we can develop for pediatric DCD at CHB. In addition, the Task Force agreed upon (1) guidelines for informed consent, (2) other guidelines for implementation of the protocol, should the Hospital determine to go forward with DCD, and (3) three institutional prerequisites for implementation. However, consensus was not reached at the end of Phase II deliberations as to whether the protocol should be implemented. As noted on the above scale, one third of the Task Force

members had significant concerns about implementing a pediatric DCD for CHB. These members represented a broad range of interests, including pastoral care, family concerns, neurology, ethics and intensive care medicine, and their opinions were not discounted. Remaining issues included:

- Child-centered versus family-centered care,
- Effects of DCD on the integrity of end-of-life care in our ICUs,
- Significance of the low number of likely DCD candidates at CHB,
- Relationship with NEOB,
- Conflict and possible conflict of interest on the Task Force, and
- Staff conscientious objection: fairness to staff, continuity of care.

The Co-Chairs of the Task Force continued to work off-line in April and May 2006 with those members most skeptical of DCD after the Phase II deliberations of the full Task Force were completed. The reasons for reservations about DCD were explored further, including possible limited circumstances under which consensus could be achieved.

Based on the deliberations from the Task Force during both Phase I and Phase II, the *Pros and Cons of DCD* (Section IV below) were distributed by the Co-Chairs to Task Force members for consideration before final recommendations from the Task Force were considered. At the final Task Force meeting in September 2006, Task Force members were asked to indicate their views on a set of five possible recommendations. The results are reported in Section V, Recommendations.

SECTION IV

PROS AND CONS OF DCD AT CHILDREN'S HOSPITAL BOSTON: ANALYSIS OF THE ISSUES

1. Introduction

2. Considerations regarding the Donor Child and Family

- 2.1 Standards for Decision Making on Behalf of Children
  - 2.1.1 First Person Consent
  - 2.1.2 Substituted Judgment
  - 2.1.3 Best Interests of the Child
  - 2.1.4 No Clear Harm
  - 2.1.5 Legal Bottom Line
- 2.2 Benefits of DCD for Families and Children
  - 2.2.1 Benefits for Families
  - 2.2.2 Benefits for Mature Minors and Young Adults who Wish To Donate Organs
- 2.3 Risks of DCD and Corresponding Protocol Safeguards
  - 2.3.1 Conflicts of Interest
  - 2.3.2 Decisions to Withdraw Life Support
  - 2.3.3 Procedures for Informed Consent to DCD
  - 2.3.4 Management of the Child's Last Hours
    - Overview
    - End of Life Care for the Living Patient
    - Determination of Death
    - Return to ICU if Donation Fails
  - 2.3.5 Diminution of Respect for the Child
  - 2.3.6 Financial Cost to the Family

3. Considerations regarding the Hospital's Overall Mission

- 3.1 Weighing of Benefits & Harms to the Hospital's Core Constituencies
- 3.2 Obligation to Support Organ Transplantation
- 3.3 Obligation to Offer a Service that can Benefit Some Families
  - 3.3.1 Can We Do it Well?
- 3.4 Protection for Staff Conscience
- 3.5 Role of CHB Vis-à-vis Other Pediatric Hospitals and Transplant Centers
  - 3.5.1 Fairness in Impact on Local Patients
  - 3.5.2 Leadership Role among Pediatric Institutions

SECTION IV

PROS AND CONS OF DCD AT CHILDREN'S HOSPITAL BOSTON: ANALYSIS OF THE ISSUES[q]

1. INTRODUCTION

To assess whether Children's Hospital should offer DCD, the Task Force considered the issues at stake at two levels of analysis: the bedside or "micro" level of the patient and family and the institutional or "macro" level of Children's Hospital as a whole. During Phase I, the Task Force had determined that offering DCD was not intrinsically right or wrong for the Hospital, but that it could be appropriate if certain conditions could be met. From that point, attention was focused on the likely effects of DCD on Hospital patients, their families, and the overall mission of the Hospital. The goal was to answer two questions, as described below.

1. *If we consider only the welfare and rights of eligible patients and families who might choose DCD, is it clinically and ethically acceptable to offer DCD under our proposed protocol?*

At the level of the bedside, the Task Force inquiry focused on understanding the likely impact of DCD on the donor child and parents, and setting parameters to keep that impact within acceptable bounds. This entailed considering the following issues:

- Generally accepted ethical and legal standards for making treatment decisions on behalf of children, and special considerations related to DCD;
- Likely benefits of DCD for donor children and families;
- Likely risks of DCD for donor children and families;
- Specific conditions that would have to be met in order to keep the anticipated risks at an acceptable level, taking into account the prevailing ethical and legal standards and our own moral culture at CHB;
- Specific safeguards that could be incorporated into a DCD protocol to address these conditions.

This analysis is taken up in Part 2 of this Section and reflected in the Task Force Recommendations, Section V, Part 1, Statements 1 and 3.

2. *Taking into account the mission of Children's Hospital Boston as a whole, should the hospital adopt a DCD protocol?*

Assuming the best-case scenario of a positive answer to the question posed in Part 2, the Task Force also considered the likely impact of adopting a DCD protocol on the overall mission of CHB. Discussion focused on both quantitative and qualitative factors, including:

[q] Section IV of the Report was prepared by Charlotte Harrison.

- Likely costs or benefits to stakeholders other than the donor child and family, to whom the Hospital has responsibilities. These include other patients and families, CHB staff, and the organ transplantation system;
- The Hospital's obligations to each of these constituencies;
- The kinds of leadership that the Hospital could or should exercise among pediatric institutions that are considering DCD.

This analysis is taken up in Part 3 of this Section and reflected in the Task Force Recommendations, Section V, Part 1, Statements 2 and 4.

Most of the foundational conditions for DCD that were identified by the Task Force in Phase I, and incorporated into the resolution adopted by MSEC, pertained to the bedside level of analysis. These are highlighted in the various subsections of Part 2 below pertaining to potential risks. Two factors from the foundational conditions – maintaining the quality of care for all patients in the ICU and honoring the moral or religious objections of CHB staff who wish to avoid participation in DCD – are matters of broader institutional priorities and are addressed in Part 3.

From the beginning, the Task Force sought to do more than take a vote on whether CHB should adopt a DCD protocol or not. Deliberations were oriented toward exploring the empirical evidence and the clinical or ethical reasons that led its members to take one position or another regarding DCD. This approach of evidence-based deliberations and justification by reasons had several goals: to ensure the full airing of relevant considerations within the Task Force; to reflect Task Force accountability to Hospital leadership; and to promote understanding of Task Force recommendations by CHB staff, families and the public. It is hoped that the evidence and reasons summarized in this report will facilitate decision-making by Hospital leadership, which is ultimately the appropriate body to weigh the sometimes-conflicting interests at stake in donation after cardiac death.

2. CONSIDERATIONS REGARDING THE DONOR CHILD AND FAMILY

If we consider only the welfare and rights of eligible patients and families who might choose DCD, is it clinically and ethically acceptable to offer DCD under our proposed protocol? With this question in mind, the Task Force discussed the following issues.

2.1 STANDARDS FOR DECISION-MAKING ON BEHALF OF CHILDREN

In the section immediately below, we review generally accepted standards for making treatment decisions on behalf of children. The mainstream ethical and legal standards track each other closely, although the ethical standards may be more nuanced because they need not be written into public policy for universal application.

A central concept in each of these standards is informed consent – the right of a patient, or the patient's proxy,[r] to make treatment choices that are voluntary and based upon full information about relevant options. Informed consent to DCD has two components. Consent to become an organ donor, after death, is one component. In addition, since DCD involves not only postmortem donation but also the medical treatment of a living person, it is necessary to have consent to premortem treatment under the particular conditions entailed in a DCD protocol.

In both medical ethics and law, competent adult patients have the right to choose for themselves among the treatment options offered by their physician. Their choice can be guided by their own subjective values and preferences. No one else need agree that they've made an appropriate choice. In medical ethics, this right of self-determination is a matter of showing respect for each individual as a human being. As some Task Force members described it, following the philosopher Immanuel Kant, it requires treating people as "ends in themselves," rather than merely as means to others' ends.

When the patient is a child, of course, the question of who should choose – and on what basis – is a more complicated one. There are three dominant standards in law and medical ethics. The child's own first-person judgment is important, if the child has adequate maturity and capacity to choose. When others must decide on behalf of the child, the widely accepted standards are "substituted judgment" – applicable when there is a basis for knowing what a mature child would have wanted, if he or she cannot make a decision currently -- and, in all other circumstances, the "best interests of the child."

2.1.1. First-Person Consent

For certain kinds of medical decisions, Massachusetts laws accord certain adult rights to "emancipated minors," who are legally and financially independent of their parents, sufficiently emotionally and cognitively mature, and living apart from their parents. Massachusetts law authorizes other, non-emancipated minors to make their own decisions in certain discrete areas, such as seeking treatment for alcohol and

[r] Throughout this report, we refer to the child's proxy as the "parents" or "family." In general, these expressions are meant to include non-familial guardians as well.

substance abuse, or certain matters related to procreation; however, Massachusetts law does not authorize such minors to make anatomical gifts. Even where a non-emancipated minor elects to be an organ donor on a driver's license, the consent of a parent or guardian, or a court order approving the donation, is necessary. Thus, unlike DCD involving adults, most of the patients who would be providing organs are not actually legally authorized to consent on their own behalf to a proposed donation. A parent, guardian, or court must consent.

Even if a child does not have legal authority to make treatment decisions for him- or herself, ethical standards call for the child's preferences to be taken into account to the extent warranted by his or her maturity and understanding. Guidelines of the American Academy of Pediatrics, for example, provide that children are to be brought into the decision-making process and asked if they "assent" to recommended treatments. Whether they assent or not, their point of view should be taken seriously.

2.1.2 Substituted Judgment

If a minor or young adult has once been mature enough to make treatment choices but is no longer able to speak for him or herself (*e.g.*, because of a traumatic brain injury), the appropriate legal and ethical basis for decision is a "substituted judgment." Under this standard, parents or other surrogate decision-makers are authorized to act on their judgment of what the patient would have wanted in the circumstances presented.

Some patients will have indicated their preferences regarding organ donation or end of life care prior to their injury. They may have entered the state organ donor registry when they applied for a driver's license. In other cases, family and friends may have a sense of the patient's values with respect to related issues, such as altruism or the importance of keeping the body intact. The desire to donate organs would be one factor in a substituted judgment about DCD; another necessary factor would be the desire, or at least the willingness, to accept the course of end of life care entailed in DCD.

2.1.3 Best Interests of the Child

Some children who would be DCD candidates at CHB would be too young for a substituted judgment standard to apply to them. In these cases, the gold standard in law and ethics has long been the "best interests of the child." This standard recognizes the vulnerability of children, particularly those who cannot speak or advocate for themselves, and seeks to protect against the possibility that adults deciding for children will be influenced by their own or others' interests, which may be in conflict with those of the child. Although the best interests standard has been criticized in the ethics literature, it remains the primary touchstone in pediatrics today.[s]

[s] This literature was surveyed by the Subcommittee on Family Views and Ethics of Proxy Consent as the foundation for its Phase II report, on which much of this discussion is based. That report, including a bibliography, is reproduced in Appendix H.

Who decides what is in a child's best interests, and on what basis should they make this decision? In theory the basis is an objective one: what would a reasonable person want for him or herself in the circumstances? In many cases, there is more than one reasonable choice. In these cases, the decision is left to a child's parents or other legal guardians, who are generally entitled to make it according to their own interpretation of how best to promote their child's welfare. This deference is based on recognition that most parents have intimate knowledge of their child's needs and feelings and a strong commitment to their child's welfare. It also acknowledges our society's respect for the privacy and integrity of the family unit and its tradition of protecting parental interests in bringing up children according to the parents' particular values.

Limits to deference

Deference to parental judgment is not unlimited, however. When the judgment is about a medical matter and clinicians will be involved in carrying it out, the clinicians have a professional obligation to consider the effect of the choice on their patient's welfare. Under the best interests test, there are at least two grounds on which a physician's medical ethics could require second-guessing parental treatment decisions:

- *Disqualification of the parent as decision-maker*. Less credence is owed to parental decisions to the extent that the parents are uninvolved with their child, hostile to the child, abusive, incompetent to make a reasoned judgment about the child's needs, or apparently acting from motives in obvious conflict with the child's best interests.

- *Abrogation of widely shared professional or societal norms.* Clinicians are not expected to honor the choice of a surrogate if it is outside the limits of "reasonableness" in assessing the child's best interests.

There was agreement in the Task Force that the "best interests" standard cannot generally be met by DCD, since patients themselves do not benefit from the procedure. It was suggested that most children would not want any intervention not necessary for their own care and would do best in the close, protective care of their families in their last hours. The Task Force did not feel that altruism could be uniformly presumed or imputed to younger children. (If mature minors altruistically wanted to donate organs, whether to benefit society or to give comfort to their families, that would be addressed under a substituted judgment standard.)

Exceptions to best interests test

The Subcommittee on Family Views and Ethics of Proxy Consent was asked to investigate whether it could be justifiable for parents to choose DCD on a basis other than the strict best interests of their child. After an extensive review of ethics

literature and conversations with several pediatric ethicists, the Subcommittee found that there are both reasons and precedents for deviating from the best interests standards when the harm to the child is genuinely minimal and/or some benefit to the child is anticipated.

As noted by the Subcommittee, the best interests standard has been criticized for giving parents insufficient latitude to take into account the interests of other parties for whom they feel responsible or whom they wish to benefit. The standard is not universally followed in practice. Two fairly common, limited exceptions are especially relevant to DCD:

- *Accommodating the needs of other family members.* The patient's vulnerability makes it imperative that his or her interests not be disregarded; however, families may be justified in giving less weight to minimal harms to the child in order to serve more substantial interests of other family members. Medical professionals accept such decisions in certain situations, such as bone marrow donation by a young child to benefit a sibling, and, in the ICU, resuscitation of a child (or other intrusive measures for prolonging a burdensome life) to allow time for family members to be present at the child's death. In each of these cases, there are also arguably benefits to the child, either in growing up with the sibling or in having the company of family members at death.

- *Choosing to benefit society*. Parents may enroll their child in research studies that cannot offer any direct benefit to him or her. This exception is carefully circumscribed in the law: the risk to the child must either be "minimal" or it must be a "minor increase over minimal risk." In the latter case it must also yield vital knowledge concerning the child's disease or condition, and involve research experiences commensurate with those inherent in the child's actual medical experience. Alternatively, if the risk is greater than minimal risk, the research must have the potential for direct benefit to the child which justifies the risk, and the risk/benefit ratio for the child must be at least as favorable as the risk/benefit ratio under available alternative therapies. "Minimal risk" refers to risks comparable to what a typical healthy child would undergo in daily life. Any deviation from these standards requires the personal approval of the Secretary of the Federal Department of Health and Human Services.

Each of these steps away from the best interests standard represents a compromise whose justification depends on its being narrowly constructed to serve an important purpose and remaining consistent with protection for the patient's basic welfare.

2.1.4 No Clear Harm

The Subcommittee on Family Views and Ethics of Proxy Consent identified an additional exception, advocated in some of the ethical literature, which might be more appropriate than "best interests" for a young child with very severe brain damage. As noted in the Subcommittee's report:

Some argue persuasively that [the best interests] standard cannot apply to patients for whom "no return to an even minimal level of social or human functioning is possible" (President's Commission), who "permanently lack the capacity for consciousness and whose good can never matter to them" and who thus have no "experiential" or "morally considerable" interests. (Buchanan & Brock) [t]

For children like this who are DCD candidates, the Subcommittee suggested, it could be appropriate to apply a "clear harm" standard, under which the parents' choice should be accepted unless there is "significant risk of serious preventable harm" to the child[u] and as long as the balance of risks and benefits is not disproportionate when compared to the other intrafamilial exceptions to the best interests standard that are already observed in practice. As long as parents' choice to withdraw life support had met an appropriate standard before DCD was considered, the "clear harm" standard would be used to determine whether the parents' choice of DCD was ethically acceptable. The standard would be met if the DCD process itself (*i.e*., the premortem procedures described below) were not expected to cause serious preventable harm to the child before, during or after the withdrawal of life support.

This approach would apply to most DCD candidates but not to those few conscious patients who may choose withdrawal of life support because of unbearable quality of life due to progressive neuromuscular disorders. For those patients, the appropriate standard would be substituted judgment, where applicable, or best interests of the child.

2.1.5 Legal "Bottom Line"

Taking into account the foregoing issues, the Office of General Counsel offered the following general advice for the Task Force:

The bottom line is that any policy should provide for effective consent for donation that meets appropriate ethical and clinical standards; that the care of patients before death is driven by undiluted service to their care; that practical conflicts between care and surrogate consent to donation need to be minimized and ethically addressed, with some careful skeptical review given to surrogate consent to premortem steps that while promoting donation may potentially harm the patient or the patient's care; that clinicians' and hospital conflicts of interest have to be completely avoided; and that the test for whether we can both serve the important goal of promoting organ donation and meet these standards should be a hard-nosed pragmatic one – as hard-

[t] See Appendix H, Ethical Frameworks. Complete references to the President's Commission report and Buchanan & Brock text cited here can be found in Appendix H, Family Subcommittee Bibliography.

[u] For the full quotation and a proposal to substitute a "clear harm" standard for the best interests standard, see D.S. Diekema, Parental Refusals of Medical Treatment: The Harm Principle as Threshold For State Intervention, *Theoretical Medicine*, 2004; 25:243-264.

nosed as a jury's review of a case in retrospect – about whether Children's can establish a way of doing it in this institution, in its specific care environment, which will in a consistent, documentable fashion show that we have done so. [v]

2.2 BENEFITS OF DCD FOR FAMILIES AND CHILDREN

Focusing primarily on the child and family, the Task Force identified several ways in which CHB patients or their families might benefit, psychologically or emotionally, from donating organs via DCD. These were informed in part by comments from CHB staff focus groups and from other institutions surveyed, which are included in Appendix C and D, and weighed against possible psychological harms that DCD participation could bring about. (Benefits to organ recipients are not included in this section, since CHB patients would be unlikely to receive the organs.[w])

2.2.1 Benefits for Families

The Subcommittee on Family Views and Ethics of Proxy Consent summarized the possible benefits of DCD to families as follows:

- *solace:*
  - *belief that child can "live on" in a more meaningful way through solid organ donation than through other means (tissue donation, pursuing child's projects, other forms of memorializing the child)*
  - *belief that they are enhancing meaning of death/death not in vain/some good will come, more than possible through other means (see above)*
- *altruism toward organ recipients and society*
- *autonomy:*
  - *opportunity to know about and choose from full range of possible options for meaning and solace at their child's death*
- *fidelity:*
  - *belief that they are fulfilling child's wish to be organ donor (if clearly indicated)* [x]

Solace and altruism

All members of the Task Force agreed that the most important reason to consider offering DCD at Children's was the opportunity to help grieving families finding solace, rather than the goal of increasing the pool of organs for donation. The Hospital's mission of providing "family centered care" counted strongly in favor of offering options that could meet each family's needs and preferences. The suffering

[v] For the full legal report, see Section II, Phase I, Report 2.2.

[w] See Section II, Phase I, Report 2.1.

[x] See Section III, Phase II, Report 2.3.

of families with dying children made this mission especially important in cases where life support will be withdrawn.

There was some difference of opinion among Task Force members regarding the likelihood that the opportunity to donate organs would provide significantly more consolation than other options for families to memorialize their child and whether asking some families would be wrong for them. Both anecdotal experience and research were considered.

Staff and family experience. Several Task Force members related first-hand experience with parents for whom donation after brain death was a great source of comfort, as well as parents who had been disappointed when they could not donate under a brain death protocol and DCD was not available. (Some of these children might have been good candidates for DCD; others did not die within the requisite hour.) Some CHB families, along with others in the published literature, have said that they feel their child lives on, in a sense, in the bodies of the organ recipients, and that altruistically helping another person to live is a way of giving positive meaning to the child's death.

UNOS provided the Task Force with a video testimonial from a mother who had found it very meaningful to donate the kidneys of her 17-year-old son under a DCD protocol. Other individuals who had donated their children's organs under brain death protocols spoke movingly in favor of donation at a Nursing Grand Rounds attended by some Task Force members. There was some discussion among the Task Force regarding how representative these views are of the general population of families who donate organs. (Those with negative experiences do not generally have the same institutionally supported opportunities to express their views.) Additionally, some focus group and Task Force members were concerned that bringing up DCD could cause greater harm than good to some families. There were first-hand reports that some parents had been offended when asked if they wished to consider donation after brain death.

Published research. In Phase I, the Subcommittee on Family and Community Views reviewed the very limited research literature on parental attitudes toward organ donation in general and DCD in particular. The Subcommittee identified one study that focused on the potential benefits of DCD in the pediatric population specifically. This article took a strong position in favor of DCD. The majority of the Subcommittee did not find the conclusion compelling. The article's basic premise (that the primary benefit of pediatric DCD is an increase in the organ donor pool) did not match the basic premise under which the Subcommittee was working: that the primary benefit is potential comfort for grieving families. There was no acknowledgment that consent by families for children entails unique ethical considerations not applicable to the competent adult DCD population.[y]

[y] Personal communication, Meg Comeau.

No follow-up studies were found on families' views of DCD after having participated, or after having declined to participate. The Subcommittee did find one poster presentation abstract on whether parents of PICU patients would want to be asked about DCD. The conclusion that parents 'overwhelmingly' do want to be asked was based on the results of a semi-structured interview with a sample of 20 parents of PICU patients who may or may not have been DCD candidates. Members of the Subcommittee expressed reservations regarding the validity of this conclusion, given the small sample size and potential bias of those interviewed. (The Subcommittee assumed that the majority of DCD candidates at CHB would be victims of trauma; 50% of those parents surveyed had children with long-standing, chronic conditions. It seemed reasonable that those parents would have a greater familiarity and comfort with difficult medical decision-making, potentially influencing their willingness to be asked about DCD.) No studies assessed whether donation of solid organs (or the kidney in particular) provided more comfort to families than other ways of memorializing their child.[z] These include

(i) donation of tissue, such as corneas and life-saving heart valves, which can be done after death without any changes in premortem care, and
(ii) pursuing projects that reflect the child's character or interests.

The Subcommittee determined that it would be difficult for the Task Force to conduct meaningful research on these questions itself in the time available.

In Phase II, with little research to go on, the Subcommittee on Family Views and Ethics of Proxy Consent identified the following possible harms to families, to be weighed against the likely benefits:

- *harms from participation in procedure itself:*
  - *physical separation from child*
  - *witnessing bedside preparation*
- *harms from offer of DCD & I/C [informed consent] discussion:*
  - *distress from being confronted with/hearing about process*
  - *disrespect or distraction of being asked to think about DCD during dying time, rather than treating that time as a gift; in some traditions, it's disrespectful to talk about death or make funeral arrangements while person is dying*
- *harms from having to decide quickly at emotional time with imperfect information:*
  - *risk of making "wrong" decision (by own stable values) because DCD is too complex to process fully, cognitively or emotionally, when child is dying*
  - *feeling uncertain that child would have wanted this or that it was the right thing to do; worry that they didn't provide dignity*

[z] Personal communication, Meg Comeau.

- *regret/more grief if the donation isn't successful: child doesn't die soon enough, organs aren't usable*[aa]

In light of these possible harms, would there be a net benefit to families from being offered DCD? With respect to the prospect of emotional harms from a preliminary offer, some members argued that these parents would already have made a far harder decision to withdraw their child's life support and that it would be unjustifiably paternalistic to prevent them from having the choice to donate or not. Others suggested that, since benefit in this case is purely a matter of the family's own perceptions, it is difficult to second-guess families' choices, as long as there is satisfactory informed consent. All agreed that any initial conversation with parents about donation should merely ask whether they would like to talk about it with NEOB and other ICU staff (who would not include the immediate care team). Parents who were not interested need consider it no further.

Primarily to protect families who would not want to be asked about donation, or who might feel pressured to agree, the Task Force considered whether to limit offers of DCD to families who raised the question of donation themselves. This "don't ask/do tell" approach was debated but ultimately rejected as imprecise, unfair and potentially discriminatory.[bb]

Family autonomy

Support for asking parents went beyond the contention that DCD could improve families' well-being. An additional factor was respect for family autonomy – for privacy and self-determination in decision-making within the family, and for the moral and religious diversity within the population we serve. For many Task Force members, the value of DCD to parents could best be gauged by offering them a chance to hear about donation and allowing them to make the decision.

To some members of the Task Force, parents have a moral *right* to choose DCD for their child, if it comports with their values, as long as the choice is fully informed and voluntary and as long as it does not violate important medical or societal standards for the protection of their child. In the view of many, pediatric DCD as outlined in the proposed protocol would not violate such outside limits. No guidelines from academic or professional societies were found to explicitly rule it out. On the other hand, the few available guidelines were focused primarily on the adult donor population. The pediatric guidelines among them contained only a brief and arguably self-contradictory conclusion: that pediatric DCD is "ethically reasonable" but that guardians' consent for children (especially those younger than 14) must be "based upon best interest of the minor."[cc]

[aa] See Section III, Phase II, Report 2.3.

[bb] For a summary of the advantages and disadvantages considered, see Section III, Phase II, Report 2.1, Consideration for Implementation.

[cc] Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine, *Recommendations for Non-Heart-Beating Organ Donation*, 2001.

2.2.2 Benefits to Mature Minors and Young Adults who Wish to Donate Organs

For some Task Force members, the concerns counting against DCD would apply primarily to younger children and might not apply if DCD were limited to mature minors and young adults as described below. Indeed, with these older patients, there could be another benefit to families who chose DCD: the satisfaction of acting in away that seemed faithful to their child's wishes.

A basic foundation of adult DCD is honoring the desire of the dying individual to be an organ donor. This consideration does not apply to younger children; however, it could support the availability of DCD to mature adolescents and competent young adults who have chosen DCD for themselves, or whose families reasonably believe they would have chosen it if given the opportunity.

What benefits might an older child derive from donating? The Family Subcommittee suggested the following possibilities:

- *fulfillment of own desire to be an organ donor, in the case of a mature minor who has indicated this desire on driver's license or donor card (but would this person want to donate in the conditions necessary to DCD?)*
- *comfort in believing that family will derive solace from donation/"living on" (hard to attribute to younger children)*
- *altruism toward unknown recipients or society (hard to attribute to younger children)*[dd]

As noted in Part 1 above, if patients are legally competent or sufficiently mature to make decisions for themselves, they have a moral and legal right to have their preferences taken into account. Even if patients have lost consciousness or decision-making capacity at the time the question of donation is raised, those who were previously mature or competent may have indicated their interest in organ donation in the past, either in conversation with family and friends or by entering their name in a state donor registry. Young people who have grown up with progressive diseases such as cystic fibrosis or Duchenne muscular dystrophy may have thought deeply about dying, and perhaps about organ donation. It is the ethical and legal responsibility of their family members or other proxies to make a "substituted judgment" on their behalf – a judgment as to what these patients would likely have chosen, based on their enduring personal values. This judgment should take into account both the patients' desire to donate and their likely preferences regarding the conditions in which to spend the final hours and moments of their life.

For this group of patients, the question posed to parents in the informed consent process would be whether they believe their child would or would not have wanted to

---

[dd] See Section III, Phase II, Report 2.3.

donate via DCD. For some Task Force members, this would put the discussion on the proper ethical footing – focusing on a substituted judgment and disallowing a decision for DCD that was based on claims that it would be in the child's best interests. Focusing on the child's own desires from the outset could also reduce the chance that parents would later feel they had betrayed their child in choosing DCD.

In the view of other Task Force members, it would be too difficult to attribute to most young people the desire to be treated as a DCD protocol would require, even if the young person had wanted to be an organ donor. It was believed that, in the understanding of most members of the public, organ donation affects only the treatment of the body after death. Only under the rarest circumstances would the ordinary person know the ramifications of being a DCD donor. For some Task Force members, the difficulty of inferring consent to premortem DCD treatment was so great that such an inference should only be made if there were first-person consent to the donation itself – if the patient had felt strongly enough about donation to take the affirmative step of signing a donor card or entering a donor registry. A parent's substituted judgment would not be acceptable.

2.3 RISKS OF DCD AND CORRESPONDING PROTOCOL SAFEGUARDS

Considered in tandem with the benefits of DCD were concerns that DCD presents a number of serious and complex challenges. In the discussion below, these are grouped according to the general aspect of DCD to which they pertain. Each section explains the specific challenges identified by Task Force members, indicates the chief points of debate, and outlines the safeguards in the protocol that are intended to address these concerns. The Task Force's eight foundational conditions for DCD are included where applicable. In most cases, members of the Task Force differed on the extent to which they believed a protocol could adequately address the issues identified. Hospital leadership is encouraged to make its own assessment on the basis of the considerations described**.**

2.3.1 Conflicts of Interest

The Institute of Medicine and other commentators on the ethics of DCD have emphasized the inherent conflict of interest that faces clinicians if they must consider two goals for the care of a single patient: the end of life care of the patient for his or her own sake, and the care of the patient's organs to enhance the possibility of successful transplantation. Within the Task Force, concerns about conflict of interest informed the discussion of most features of the process required to carry out a DCD protocol. The underlying reasoning is explained in this section of the report. Details regarding specific features of the process are discussed in the sections below.

Challenges

Promoting the welfare of the patient, consistent with appropriate clinical standards and practices, is the preeminent professional responsibility of clinicians. In the course of doing so, they of course must abide by applicable laws, policies and regulations, promote patient

interests in a culture of family-centered care in which the parents have certain legal rights as well, and act within a medical community with diverse actors, including an organ donation network that generally promotes DCD. But all that having been said, in an individual case, within the matrix of such laws, regulations and policies, it is to the patient, not the family member *per se*, that the fundamental duty lies. The law protects a physician's ability to act in the patient's interest where a parent's decision-making would be abusive or medically neglectful. Adherence to this duty both engenders and justifies the trust of patients and families in their caregivers, which is crucial to the therapeutic effectiveness of clinical practice.

From a legal perspective, even in pursuing a goal as important as organ donation,

> *"[a]ttending physicians still owe an undiluted and single-minded duty of care to their patients, which may not be compromised by conflicts of interest. This is reflected, for example, in legal requirements that patients and families be approached for donation by OPO staff independent of the attending who will declare death…. Even consent would not suffice for surrogate consent situations in which the harm to the patient from procedures solely to promote organ preservation and donation could not be ethically defended, nor of course can a person consent, for themselves or others, to actions which would violate the "dead donor rule."* [ee]

In that portion of the DCD process that was the focus of this Task Force, the patient is a living child -- a person entitled to be treated according to professional standards of care. (The protocol for actual organ removal, after the child's death, was not at issue.) Yet participating in a DCD protocol requires the hospital and some clinicians to give consideration to the interests of parties other than the patient. These include:

- *The family of the dying child*, whose own emotional needs may be served by focusing on the possibility that the child might "live on" through organ donation**.**
- *Prospective organ recipients*, for whom both the quantity and quality of organs retrieved, are important. (This conflict of interest may be attenuated in DCD at CHB because organs procured here are unlikely to go to CHB patients.[ff])
- *The organ bank*, whose primarily obligation is to encourage and facilitate donation.
- *The hospital itself*, which benefits from its role as a transplant center, as do the families that center serves.[gg]

[ee] See Section II, Phase I, Report 2.2. The "dead donor rule" is the principle that organ donors must be dead before their organs are procured – that donation must not be the cause of their death.

[ff] See Section II, Phase I, Report 2.1.

[gg] The IOM observed that an institutional bias toward improving the supply of donor organs may be difficult to completely resolve by any conflict of interest safeguards" because of staff awareness of the "possible benefits in prestige, research support, patient care reimbursement, and staff recruitment that may accompany a successful,

To the extent a clinician or family member has the interests of any of these parties at heart, or is affected by pressure from any of them to give priority to organ donation over the interests of the dying child, the process may be affected by a conflict of interest.

Two of the Task Force's foundational conditions addressed this problem in general:

> #4 – CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but the **implementation of the protocol will not alter the quality of care in the ICU or the trust of families that the welfare of their child is their and the staff's paramount concern.** DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.
>
> #3 – There will be rigorous oversight of protocol development and the subsequent implementation. **Resources will be made available to ensure independent oversight and monitoring of the DCD process and outcomes, with controls and authority established to prevent conflicts of interest,** variance from the established protocol, and violations of any of these eight foundational criteria**.**[hh]

Other criteria were targeted to specific stages of the DCD process, as described in subsequent sections of the report.

What actual harm might such conflicts of interest bring about? In DCD, specific aspects of a child's care that could be affected by transplantation-related considerations would include the following:

- The decision to withdraw life support
- Management of the child's end of life care (location, interventions, timing)
- Determination of death (location, methods, timing)
- Care for the child after withdrawal of life support if donation is not possible

These aspects of the DCD process are discussed in Subsections 2.3.2 and 2.3.4 below.

More generally, some Task Force members feared that ICU patients might begin to be seen as prospective organ sources as well as dying children, and that this could lead to an erosion of respect for and sensitivity to all the children cared for there. Concerns for the dignity of children are discussed in Subsection 2.3.5.

---

growing transplant program." Institute of Medicine, *Non-heart-beating Organ Transplantation: Medical and Ethical Issues in Procurement*, National Academy Press, 1997: 56.

[hh] Relevant portions of the foundational conditions are highlighted in bold face. Other portions may be highlighted in other sections of the report.

Debates and safeguards

It was generally agreed that these conflicts are inherent in the situation and thus cannot be eliminated entirely. To some Task Force members, however, the staff conflicts of interest involved in DCD are no worse than other conflicts that seem to be managed adequately in our ICU's, such as the financial conflict that can arise from knowing a child's insurance status or the professional conflict that can arise from recruiting a patient to participate in a clinical trial run by the treating physician. Other Task Force members worried that the competing interests in DCD would be even more immediate than these, especially when grieving parents and dedicated OPO representatives were present as care decisions were being made.

In addition, there was concern that, even if decision-makers gave appropriate priority to the interests of the dying child, there could still be an *appearance* of conflict of interest -- a perception by families that clinical staff are more interested in helping individuals on the transplant list than in ensuring the best end-of-life care for their child. Some Task Force members worried that the appearance of conflict would be inevitable in the mere act of asking families if they would like to consider donation, since this would follow closely after discussions of withdrawing life sustaining treatment. Also, families' suspicions might be exacerbated if they observed the presence of the OPO on the floor and perceived that the OPO has an influence on decisions involving the premortem care of their child. Others argued that these problems could be minimized if handled carefully as detailed in the protocol.

Specific protocol safeguards were addressed to the specific stages of the DCD process, as described in the subsections below. One general safeguard would be applicable to all stages of the process:

> *Oversight of the entire process should be conducted by individuals who are present at the time and who have the authority and willingness to alter or stop the process if there are protocol deviations or if other ethical questions are raised by staff members in the moment. The Task Force suggested that these individuals be senior clinicians appointed by the Medical Staff Executive Committee. The protocol and implementation guidelines also call for structured review after each donation and independent review periodically to promote accountability. [This review is to include unit specific M&M and Bereavement Council meetings, as well as OR and ICU governance committee reviews, with reports to be forwarded to the Task Force co-chairs and shared with senior leadership of the Hospital.] Staff or families will also be free to request an ethics consultation at any time, as is standard policy within the Hospital.* (Protocol 2B; Considerations for Implementation 1, 2 and 6)[ii]

[ii] All references to specific safeguards in this Part of the Report are to provisions of the Protocol and Considerations for Implementation, found in Section III, Phase II, Report 2.1. Language in italics is quoted from the provisions cited.

Following the first two DCD cases or 12 months, whichever came first, the Task Force called for senior leadership to decide "whether to continue or modify the DCD program." (Considerations for Implementation 6)

2.3.2 Decisions to Withdraw Life Support

Patients have the moral and legal right to forgo life sustaining treatment, just as they may refuse other medical interventions. Withdrawal of life support is a common occurrence in our ICU's, involved in up to 90% of ICU deaths. In pediatrics, it is essential to the ethical and legal integrity of decisions to withdraw life support that they be based on the best interests of the child (or, in rare cases, a mature child's own judgment or parents' substituted judgment for such a child).

Challenges

In order to preserve the integrity of these decisions despite the conflicts of interest involved in DCD, IOM and many other commentators have emphasized the importance of ensuring that the decision to withdraw life support continues to be based on the accepted ethical and legal criteria alone, independently of the decision to donate the child's organs. The Task Force emphasized this concern in its foundational conditions 1 and 4:

> **#1: Each child** [who is considered for DCD] **will be an appropriate candidate for withdrawal of life support under circumstances not involving the prospect of organ donation.**
>
> **#4:** CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but the **implementation of the protocol will not alter the quality of care in the ICU or the trust of families that the welfare of their child is their and the staff's paramount concern.** DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.

Most members of the Task Force expressed confidence that currently, in the absence of a DCD protocol, decisions to withdraw life support at CHB are made with care and integrity. Task Force members generally agreed that ICU's at CHB currently allow ample time before withdrawing life support for staff to feel confident of the child's diagnosis and prognosis and for family members to come to a decision they feel is right for the child. Also, it was suggested that "checks and balances" against premature or inappropriate withdrawals of life support are built into ICU decision-making by virtue of staff rotations and shift changes, which mean that children are cared for by numerous clinical team members during their ICU stay. It was said that ICU staff members generally feel free to raise concerns about any child's care, whether by discussing it with colleagues or their ICU director or requesting an ethics consultation.

The prospect of introducing DCD into this system caused some members to worry that staff attitudes toward and treatment of dying children might be affected for the worse. Concerns were expressed about the following interrelated considerations.

- *Intrusion of organ donation considerations into discussions regarding withdraw of life support.* In theory, the independence of these issues could be protected by separation in time: staff could simply wait until after families have decided to withdraw life support before asking them if they are interested in talking about organ donation. In practice, however, ICU attendings on the Task Force doubted that this independence could be maintained. Clinician-family communication cannot, and perhaps should not, be fully controlled by the clinician. Families may ask about organ donation at any time, even before the subject of withdrawing support has been discussed. Would it be possible to keep the discussions independent?

  One intensivist presented the following difficult scenario: suppose that, when the attending brings up the subject of withdrawal of life support, the family asks immediately if they will be able to donate organs. Suppose that a true answer to that question is that it may depend on timing, that donation might be possible if life support were withdrawn that same day, but it is unclear whether the organs would be in adequate condition if withdrawal occurred in a week. What should the intensivist say to the family?

- *Premature judgment about a child's neurological prognosis*. Neurological prognoses in children can be especially difficult because of the resilience of children's brains. Yet in most cases where a child would be a DCD candidate, severe and irremediable neurological injury is fundamental to the justification for withdrawing life support.

  The prospect of participating in DCD could result in pressure (however indirect, unintended or self-imposed) to shorten the time a family would wait before deciding whether to withdraw life support, and that this could put a child at risk who might otherwise eventually recover sufficient function for a quality of life that would be worth living from the child's point of view. If families or staff were bent on increasing the odds of successful donation, families might feel they should withdraw support sooner rather than later in order to improve the quality of the organs provided for transplant.

- *Discrimination against disabled patients.* A focus on facilitating DCD could subtly cause ICU staff to raise the threshold at which they regard a brain-damaged child as being a suitable candidate for withdrawal of life sustaining treatment. In recent Western history, atrocities have been committed against disabled people because their lives were judged to be of limited value. It is important to guard against "creep" in the direction of ending the life of one person (here, the dying child / organ donor), from whose standpoint a circumscribed quality of life may still be worthwhile, in

order to benefit another person (the organ recipient), whose life may be more satisfying according to conventional criteria. In DCD, the possibility of providing comfort to a grieving family and supplying kidneys to needy recipients could act as powerful incentives to devalue the life of the dying child.

- *Parental mistrust of CHB staff*. Parents might perceive that staff have a conflict of interest if they are asked about organ donation too soon after discussing withdrawal of life support, or if they observe OPO representatives on the ICU floor, examining the patient's chart or discussing the patient with intensivists. The appearance or reality of conflict of interest could damage families' trust that CHB staff are giving first priority to the welfare of their child.

  Mistrust could adversely affect several important goals: the therapeutic effectiveness of relationship between clinical staff and the patient or family; the family's ability to feel confident they have done the right thing for their child in choosing to withdraw life support (diminishing possible doubts or regrets); or the family's interest in donating organs or ability to take comfort in donation.

- *Erosion of staff focus on the welfare of the child*. If there is a DCD protocol, clinicians themselves will inevitably begin to think about DCD when the possibility of withdrawing support arises. In fact, the model protocol designed by the Task Force *requires* ICU attendings to review the principal contraindications for DCD before talking with any family whose child may be a candidate for withdrawal of life support. This prescreening is intended to serve two important purposes: to reduce the presence of the OPO and to enable the physician to know whether he or she should follow a discussion of withdrawal of life support by asking family members about their interest in donation, and how to respond if the family asks about donation themselves. Nonetheless, it could have the undesirable side effect of putting DCD front and center whenever consideration is given to the withdrawal of life sustaining treatment.

Debates and safeguards

The following safeguards were established in the protocol , suggested in implementation guidelines or recommended by some members of the Task Force:

- *Prescreening of patients that minimizes NEOB involvement before family indicates interest in donation.* The protocol specifies certain absolute and relative clinical contraindications for DCD, as determined in collaboration with the NEOB. These contraindications are to be used as first-level screening criteria by ICU staff, before they have a conversation with a family about withdrawal of life support from their child. If there are clear contraindications, it will not be necessary for NEOB to become involved at all. In other cases, prescreening by phone should make it unnecessary for NEOB to be present physically in the ICU until after a family indicates interest in hearing about DCD. (Protocol 2.1-2.2)

- *Careful attention to sensitive ways of conducting conflict-ridden conversations with families.* The Hospital's PERCS program (Program to Enhance Relational and Communication Skills) should be enlisted to work with ICU staff in formulating ways of responding to family questions about organ donation that arise in conjunction with discussions of withdrawal of life support and working with the family to determine an ethical course of action for their child. This would be done in advance of implementation, and training would be provided to all staff who might be involved in DCD. (Considerations for Implementation 1)

- *Limitation of DCD to mature patients who have unequivocally indicated their desire to donate*. Some Task Force members favored offering DCD only for mature patients who had signed donor cards or entered donor registries. They reasoned that this approach would (i) remove DCD from consideration for all young children, thereby avoiding the need to screen all children for whom withdrawal of life support was being considered,[jj] and (ii) justify DCD on the basis of the patient's own desire to donate, thus aligning some of the otherwise-conflicting interests at stake. Most members felt that there was a particularly strong case for DCD with respect to mature patients who had given first person consent, even if that consent was only to the postmortem donation component of DCD. In these cases, donation could fairly be seen as a real benefit to the patient (see Subsection 2.2.2 above) and honoring the patient's wish would make the DCD process more consistent with the patient's dignity (see Subsection 2.3.5 below). This approach was rated by the full Task Force as reported in Section V, Recommendations, Statements 1 and 3.

The Task Force considered one other way to avoid or reduce some conflicts involved in decisions to withdraw life support. That was to offer DCD only if families ask for it themselves. This approach was rejected for the reasons stated in Considerations for Implementation (Section II, Phase II, 2.1).

2.3.3 Procedures for Informed Consent to DCD

Challenges

Task Force concerns regarding informed consent focused on two anticipated problems. One was the difficulty that families might have in understanding what is different about DCD -- the complex comparisons between conditions surrounding the withdrawal of life sustaining treatment in ordinary circumstances and in DCD. The second was the possibility that pressures related to conflicts of interest might have an inappropriate influence on families. For example, if asked to consent to donation by their immediate care team, families might feel obligated to consent out of gratitude, deference, or fear that the team's displeasure at refusal would affect the care of their child. A similar effect might occur if they believed that organ bank requestors were affiliated with the Hospital.

[jj] The objection to widespread screening to identify a very small number of DCD candidates is discussed in Part 3, Subsection 3.1.

Since the Task Force's support for DCD was grounded primarily in its benefits for the family, it was felt that the involvement of organ bank requestors should be carefully delineated so as to maintain the focus of consent conversations on helping the family make a decision that was right for them. There was concern that this principle would come in conflict with the clear and singular mission of organ bank requestors to increase the number of organs donated.

The Task Force's foundational conditions for informed consent provide as follows:

> #4 – CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but the implementation of the protocol will not alter the quality of care in the ICU or the trust of families that the welfare of their child is their and the staff's paramount concern. **DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.**
>
> **#5 - Participating families will give genuine informed consent that includes a statement that parents can change their mind at any time in the process. They will be informed of (i) the differences between the orchestration and experience of death, for both their child and themselves, if their child is going to be a DCD donor or not, and (ii) other facts likely to make a difference in their decision (*e.g.*, the likelihood of the organs going to another child?).**

Debates and safeguards

Some Task Force members worried that, since most families would never before have participated in the withdrawal of life support from a child, they might have difficulty understanding what DCD would be like and giving genuine informed consent, particularly at such an emotionally draining time. Others felt this would be no more difficult than giving consent to withdraw life support in the first instance.

For some Task Force members, the conflicts of interest for clinicians involved in DCD seem most comparable to those experienced by physician-researchers who are both treating patients and offering them opportunities to participate in clinical trials. This area of conflict has been closely scrutinized by ethics commentators and legal authorities, particularly because of past egregious abuses by physician-investigators and their institutional research sponsors in such cases as the Tuskegee Syphilis Study and the Willowbrook study of institutionalized children. In research, the informed consent process is highly regulated, with the aim of diminishing the effects of the physician's conflict of interest on the adequacy of the patient's informed consent.[kk]

[kk] For example, at CHB, ICU physicians are not allowed to ask their patients or patients' families whether they would like to participate in trials for which the physician is a principal investigator. In addition to seeking to manage conflicts of interest and mandating certain disclosures, the legal protections for research subjects include a requirement that institutional research ethics committees review all proposed research protocols to assess whether the prospective benefits of the study for society outweigh the likely burdens to the research subjects. In a sense, this Task Force's assessment of DCD constitutes a similar review.

In the DCD protocol and informed consent guidelines, these issues are addressed as follows:

- The initial approach to the family will be made by the attending physician. If the family wishes to discuss organ donation, a separate ICU team and NEOB representatives will be called. The child's immediate care team will not be involved in requesting consent for donation. The relationship between the organ bank and the Hospital (particularly the fact that the organ bank is a separate organization with a unique mission) will be made explicit.
- Full disclosure will be made of all specifics of the DCD process that might be germane to a parent's decision
- The family can change its mind about donation at any time, including after the declaration of death in the OR.[ll]

The Task Force also recommended follow-up with families, in the course of bereavement care, to learn how they felt about their decision afterwards and whether other information would have been helpful to them.

2.3.4 Management of the Child's Last Hours

2.3.4.1 Overview

General issues regarding this aspect of the DCD process are summarized just below. In the subsequent subsections, we take up three specific areas of concern: end of life care for the living patient before and during the withdrawal of life sustaining treatment; the determination and declaration of death following such withdrawal; and the return of a child to the ICU, after withdrawal in the OR, in the event the child was unable to donate organs. There the specific worries of Task Force members are identified, issues debated by the Task Force are summarized where applicable (in some areas there was no significant debate), and the specific safeguards addressing these concerns are listed.

General challenges

Once the decisions have been made to withdraw life support and pursue DCD, the premortem and immediate postmortem care of the child present a tension between two important goals:

- *Patient care*: for the sake of the living patient/donor, end of life care must be managed in accordance with professional standards, ensuring comfort and dignity for patients, protecting them from interventions that might hasten their death in order to benefit others, and ensuring that they are dead by legal and ethical standards before organ procurement begins.
- *Organ preservation*: for the sake of successful donation, end-of-life care should be managed so as to preserve the organs as well as possible, keeping in mind that "the best organs are those that are perfused by warm, oxygenated blood up to the very

[ll] See Protocol 2.3; Informed Consent Guidelines, Section III, Phase II, Report 2.4.

moment of their removal from the donor's body"[mm] and ensuring that there is the shortest possible time between the cessation of circulation in the living patient and the initiation of pre-procurement procedures to preserve the kidneys.

Concern about this tension is reflected in several of the Task Force's foundational conditions:

> **#2 -The withdrawal of life support process will be consistent with established practices at CHB, and there will be no physical harm, suffering or hastening of death to the child by the DCD process / protocol. The withdrawal of life support will be conducted in a compassionate and sensitive fashion that respects and preserves the human dignity of the patient.**
>
> #4 - CHB will work with the NEOB to find mutually agreeable ways of proceeding with DCD, but **the implementation of the protocol will not alter the quality of care in the ICU or the trust of families that the welfare of their child is their and the staff's paramount concern**. DCD will be an option for some families, but none will be pressured to see organ donation as an obligation or expectation.
>
> **#6 - The child will clearly be dead, which implies no potential for cognition before organ removal takes place, and our criteria for declaring death, including our concept of "irreversibility," will be ethically and medically justifiable.**

Two of these conditions refer specifically to the possible hastening of a child's death. The hastening of death is a particular worry in DCD because a patient's eligibility to be a DCD donor depends in part on the patient's dying within an hour of the withdrawal of life support. Thus, the Task Force sought to establish safeguards against conflicts of interest in the management of interventions that could affect the length of time it takes a child to die and in the choice and interpretation of measures to determine that death has occurred.

General safeguards

General protections against conflicts of interest at this stage of DCD are called for in Protocol 2.1:

> *Intensive care staff will continue to manage the patient prior to withdrawal of life support and organ procurement, ensuring complete analgesia and comfort for the patient. The NEOB and transplant surgeons will not be involved or alter patient management. Possible changes in care due to DCD will be discussed in general with the family as part of the informed consent process.*

[mm] Institute of Medicine, *Non-heart-beating Organ Transplantation: Medical and Ethical Issues in Procurement*, National Academy Press, 1997: 8.

In addition, to guard against problematic decisions that might be made in the pressure of the moment – a concern raised by internal focus groups as well as Task Force members – the Task Force agreed upon specific parameters for each major component of the process. These are detailed below.

2.3.4.2 End of life care for the living patient

Once a family has elected to proceed with DCD, the Protocol Subcommittee estimated that it would be likely to take 6-12 hours to confirm eligibility to donate, find a recipient or accepting OPO and transplant center, and schedule the necessary operating rooms and staff. During that time, before life support is withdrawn, the child would need to be kept comfortable and any interventions in anticipation of donation would have to be consistent with avoiding the hastening of death or other harms to the child. Several kinds of intervention and related issues were debated by the Task Force

A. ***Administration of drugs to increase blood flow to organs***

Challenges
Measures most commonly employed to prepare a living donor for DCD include the administration of anticoagulants (*e.g.*, heparin) or vasodilators (*e.g.*, phentolamine) in order to increase blood flow to the organs. Either class of drug might hasten death.

Safeguards
Without debate, the Task Force approved only the use of heparin and only in the last moments before death, in patients who met strict blood pressure guidelines. (Protocol 6.6)

B. ***Interventions that could require additional analgesia***

Challenges
A more subtle question concerned the possibility that donation-oriented interventions (aimed at keeping the patient alive until donation arrangements were made) would require increased use of analgesics such as morphine to keep patients comfortable. Two principal concerns about these measures were that they could interfere with relational opportunities between child and family or hasten the child's death.

- *Diminishing relational capacity*. Whether or not death was hastened, excessive analgesia could cause unnecessary drowsiness. This could interfere with any capacity the child might have to communicate with or otherwise relate to loved ones.
- *Hastening death*. Although such drugs can affect respiration and thus arguably hasten a patient's death, their use in a dying patient is ordinarily justified, ethically and legally, if intended to relieve the patient's pain or discomfort and if given in quantities that are titrated to that purpose. In contrast, giving a large bolus of such a drug, beyond the amount needed for analgesia, would be regarded as active euthanasia, which is unacceptable both ethically and legally.

In the context of DCD, ICU attendings would be expected to follow their usual standards for pain control. Suppose, however, that the patient were put at greater risk for pain because of donation-related interventions such as the administration of large amounts of fluid or the escalation of mechanical ventilation. If such interventions required the administration of additional amounts of analgesics/morphine, for example, it would be unconscionable to withhold them, since a paramount goal is to keep the patient comfortable. But would death be hastened unjustifiably by the donation-driven choice to alter the child's care, thereby setting in motion a chain of events requiring extra sedation? With this in mind, would staff hesitate to provide adequate pain control?

Debates
Points of view expressed on the use of these interventions may be summarized in three positions:

- To some members of the Task Force, such a situation would not be ethically troubling as long as the intent was not to hasten death and the child did not experience pain or suffering. In any event, it might be argued that the DCD process overall would extend the patient's life rather than shorten it, since the process involves a delay of several hours after the decision to withdraw life support is made.
- To other members, any *de facto* shortening of the life in pursuit of DCD, even if not intended to shorten life, would violate important moral, religious or professional strictures.
- To still others, allowing such practices would be both morally troubling and administratively unwise, because it could blur the line between passively allowing a child to die from his or her underlying condition and actively contributing to the death – a bright line that legitimates the withdrawal of life support and avoids active euthanasia.

Safeguards
The protocol prohibits pre-mortem interventions that may hasten death or cause harm to the patient. It draws a distinction between minor interventions, which are permitted with family consent, and major interventions or escalations, which are not allowed if they are intended only for organ preservation and would not benefit the patient directly. Examples of disallowed interventions are listed to clarify the distinction intended and promote consistency in implementation. (Protocol 2.1-2.2)

C. *Premortem insertion of cannulae for immediate postmortem exsanguination, cooling of the body and infusion of preservative solution.*

Challenges
Some DCD protocols call for the premortem insertion of cannulae to be used for administering organ-preserving cooling solutions as soon as death is declared. The Task Force reasoned that insertion of these relatively large catheters could cause discomfort to the child, alter the child's appearance in a way that could disturb the family, and affect the parents' ability to hold and comfort the child around the time of death.

Safeguards
The protocol rules out premortem cannulation. (Protocol 4.2)

D. ***The patient's environment at the time of withdrawal of life support***

Challenges
Many DCD protocols call for withdrawing life support in an OR, with the patient already prepped and draped, so that the first steps in procurement can proceed as soon as the child is dead. Parents are required to leave the child immediately after death is declared. A major concern of the Task Force, from its earliest meetings, was that such an arrangement would be inconsistent with the family's holding the child (providing comfort to the child and to themselves) and taking part in personal or religious rituals that they might otherwise wish to observe around the child's death. There was also concern among some members that the child might have some residual awareness of separation, or of the general coldness and sterility of the OR environment.

Safeguards
To humanize the OR setting, the protocol calls for the use of two adjacent ORs, one of which functions as an anteroom for extubation, where family can be present and hold their child if they wish. Music, rituals, and other observances can be facilitated as if in an ICU room. ICU staff stay with the family. After the declaration of death, the child is wheeled out of the room but the family can remain there or return to the ICU, chapel or another space if they wish. (Protocol 6.2-6.5)

2.3.4.3 <u>Determination of death</u>

Pressure on staff to declare death prematurely was a concern raised by internal focus groups and taken up by the Task Force. Other issues surrounding the declaration of death fell into two categories: defining death appropriately, and finding a reliable way to confirm the death that is not too difficult for a family to watch.

A. ***Pressure for premature declaration***

Challenges
Conflicts of interest could generate pressure to declare death prematurely. For example, staff may find it hard to observe protocol rigidly when the family wants very much to donate and the child is still living near the end of the one-hour period after extubation in which DCD is possible.

Safeguards
The protocol provides for the declaration of death to be made by an ICU attending or fellow, without involvement of transplantation staff. (Protocol 6.7)

B. *Definition of death*

Challenges

As analyzed by the Task Force, two elements are necessary to achieve certainty that a child is actually dead before organ retrieval begins: meeting the legal and ethical criteria for death (specifically, that there be "irreversible cessation of circulatory and respiratory functions"[nn]) and meeting humanitarian criteria that the patient have no residual potential for cognition. The precise meaning of these criteria is not self-evident or, in some cases, widely agreed upon in the field.

Debates

The Subcommittee on Time of Death investigated the biomedical meaning of the applicable criteria and the best ways to assess whether these criteria had been met. The Task Force debated the ethical criterion of "irreversibility" with regard to circulatory and respiratory functions.

"Irreversible" cessation of circulation and respiration. Under this definition of cardiac death, two findings are required: that circulatory and respiratory functions have ceased, and that this cessation is irreversible. Both of these findings depend on medical criteria, and the finding of "irreversibility" must meet legal and ethical criteria as well.

From a medical standpoint, after an extensive literature review, the Subcommittee on Time of Death concluded that acirculation would be the logical marker of cessation of circulatory and respiratory functions.[oo] The Protocol Design Subcommittee and the Task Force as a whole concurred. The term "acirculation" is used to indicate that there is no ejection of blood from the heart and no systemic perfusion. While "asystole" refers to the absence of myocardial contraction and ejection, during resuscitation it also implies the absence of electrical activity. Residual electrical activity of the heart, as seen on the electrocardiogram, may persist for a short time once the heart has stopped beating, *i.e.,* there is complete electro-mechanical dissociation; despite ECG activity (usually very slow, disorganized and wide complex), it is totally ineffective because it does not lead to contraction of the myocardium and ejection of blood.

How much time after acirculation should be allowed to transpire before the child's death would be irreversible from both a medical and an ethical standpoint? There is debate regarding the meaning of "irreversibility" in the ethical literature. There are at least three possibilities:

- Resuscitation has not been successful, or would not be successful if tried
- Resuscitation won't occur spontaneously
- Resuscitation won't be tried (on morally justifiable grounds)[pp]

[nn] Uniform Determination of Death Act, 1981.

[oo] For the Subcommittee's report, see Section III, Phase II, Report 2.2.

[pp] See Institute of Medicine, *Non-Heart-Beating Organ Transplantation: Practice and Protocols*, National Academy Press, 2000: 24.

The criteria established by the Task Force are intended to satisfy both the second and the third alternatives, which are consistent with general clinical and ethical understandings and practices, in a hospital setting, in circumstances not involving organ donation. When families make a decision to withdraw life support in order to allow a child to die, that decision entails a judgment that it would not be in a child's best interests for resuscitation to be attempted. Thus, the first alternative is inapplicable to controlled DCD (though applicable to "uncontrolled" DCD donors). For purposes of controlled DCD, the Task Force determined that there should be both a morally justifiable decision not to try resuscitation (entailed in the decision to withdraw life support) and an evidence-based medical judgment that resuscitation would not occur spontaneously. Issues regarding the justifiability of the decision to withdraw life support were discussed in Subsection 2.3.2 above. The Subcommittee on Time of Death concluded that spontaneous resuscitation would not be expected to occur after two minutes of acirculation.

Possibility of cognition or awareness. Task Force members sought to be sure that the donor child would not suffer any pain or other aversive experience around the time of death. Since cardiac death would not coincide perfectly with brain death, members asked whether a child could experience any physical or emotional suffering as a result of having residual cognitive capacity around the time of death or even the time of organ removal.

The Subcommittee on Time of Death conducted a review of the literature on both pain perception and near-death experience by pediatric and adult survivors. They concluded that patients lose consciousness in less than a minute after acirculation; after five minutes, patients would feel no pain and cognition would be "unprecedented."

Safeguards
The protocol provides for a waiting period of five minutes following asystole before death is declared. In the event of autoresuscitation during this period, which is regarded as highly unlikely, the donation effort will be cancelled. (Protocol 6.9)

C. *Confirmation that the child has died*

Challenges
Establishing with certainty that a child is dead can be in tension with managing the child's and family's experience with the sensitivity sought by the Task Force. Except in the situation in which a child has an arterial line in place for reasons independent of the decision to donate, confirmation of the physical findings requires echocardiography. Although non-invasive, echocardiography is nevertheless a procedure that involves placing a probe with gel onto the patient's chest to examine heart function. This could be problematic from the perspective of the patient or family experience. There was also concern that the ECG monitor might show more than a flat line at the time that death was declared, even though residual activity would cease before procurement began. If parents saw the display, it might be difficult for them to accept that their child was dead.

Debates
The Task Force discussed the technique of performing the echocardiogram and their concerns for the patient and family. It was concluded that ensuring an accurate determination of death was of overriding importance, and that at present the use of the echocardiogram could not be avoided.

Safeguards
Protocol 6.7 provides for confirmation of death by two measures of acirculation:

- *Palpation of pulses and auscultation of heart sounds, in combination with*
- *Loss of ejection and pulsatility on the patient's arterial line if in place prior to withdrawal of life support, or*
- *Absence of myocardial contraction and ejection by echocardiography.*

In addition, informed consent guidelines include the following requirement:

> *It should be clearly stated how participation in this protocol would change the care from what they would receive if they did not participate.*[qq]

The use of echocardiography is another factor to be disclosed to parents in the informed consent process and weighed by them in deciding whether to choose DCD for their child.

2.3.4.4 Return to ICU if donation fails

Challenges
DCD is not feasible if the donor does not die within a limited period of time after the withdrawal of life support. The CHB proposed protocol sets the time limit at 1 hour. UNOS data suggest that approximately one-third of patients for whom DCD is attempted will still be living at the end of the prescribed time. In these cases, donation cannot occur. The children and family will need continuing care outside the OR environment.

There was also a concern that some children might die in a hallway or elevator, in transit back to the ICU. This would be an indignity and a hardship for both child and family.

Safeguards
For these patients and their families, Protocol 7 calls for a familiar nurse and ICU room to be available for the child and family after the hour has elapsed, so that they can spend the child's remaining moments or hours in a supportive environment.[rr]

[qq] See Section III, Phase II, Report 2.4.

[rr] To support the family whose child *does* donate organs, the protocol provides that the child's ICU room be kept available until the family goes home, so that they can wait there during organ procurement or see their child there afterwards. The chapel or a private waiting room may also be available to the family. (Protocol 7.1.5-7.1.6.)

2.3.5 Diminution of Respect for the Child

In light of the protocol provisions described above, Task Force members agreed that, if the proposed protocol were followed at CHB, child-donors should not suffer any hastening of death or other physiological or psychological harms from the foregoing stages in the process. There were differences of opinion, however, as to whether even the best DCD protocol would inherently violate the dignity of the dying child by using the child's body for the benefit of another person without the child's own consent.

All members acknowledged the importance of maintaining the human dignity of the child and family, avoiding treating the child as a source of organs rather than a human being, and helping arrange a good and dignified death for the child. There were, however, different interpretations of what these concepts mean.

- *DCD diminishes dignity.* To some members, DCD intrinsically entails a diminution in the respect and dignity accorded to the dying child. To these members, even if there is no physiological or psychological harm involved the alteration of the last hours of a patient's life for the benefit of someone else amounts to using the person as a mere means to an end, unless the person has given consent. These members also found it discomfiting, if not offensive, for the surgical transplant team to be in the unavoidable posture, during withdrawal of life support, of "waiting for the child to die" in the adjacent OR. Finally, if the child did not die during the 1-hour period prescribed for DCD, there would be the unavoidable return trip to the ICU, during which the child could die on a gurney in a hallway rather than in the parents' arms. Such arrangements would be both violative of the child's dignity and incompatible with a spiritual experience of death for some children and families. These Task Force members saw in this combination of factors an abrogation of the Hospital's primary obligation to the vulnerable, dying child.

- *DCD does not diminish dignity.* Other members argued that there is no clear medical or societal consensus in this country about the meaning of dignity or of a good death, and that there is enough positive agreement on the value of organ donation that families should be able to choose DCD if it comports with their own understandings and values – assuming they have been given full information and time to consider it carefully. In particular, some members thought it plausible for a parent to believe that dignity was conferred by the act of giving an organ that could make a substantial difference in the quality or length of life of another human being. They argued that parents, who must live with their child's death for the rest of their lives, have the greatest stake in determining the circumstances surrounding that death. They also noted that, even when DCD is not a factor, we medical professionals "allow" parents to decide not to hold their child, or even be present with their child, when life support is withdrawn.

Most members in both camps agreed that, if a mature child or young adult strongly wished to donate organs, the honoring of that wish would lend dignity to the DCD process and would show respect for the patient's self-determination.

2.3.6 Financial Cost to the Family

One of the Task Force's foundational conditions for the acceptability of DCD was as follows:

#8: There will be no extra financial costs to the family from DCD participation

The Subcommittee on Financial Considerations met with representatives of CHB Finance and NEOB. It was agreed that this goal should be achievable, as long as appropriate commitments were made by NEOB and the Hospital. The Subcommittee's report appears in Section II, Phase I, Report 3.3.5.

3. CONSIDERATIONS REGARDING THE MISSION OF CHILDREN'S HOSPITAL BOSTON AS A WHOLE

As just described in Part 2, many Task Force members concluded that DCD could offer benefits to mature patients or their families if they wished to donate organs and succeeded in doing so. Assuming that DCD could be a beneficial choice for some patients and families, the Task Force also took up the larger picture of the place of DCD in the overall mission of Children's Hospital. At this level of analysis, the question was the following: *Taking into account the mission of Children's Hospital Boston as a whole, should the hospital adopt a DCD protocol?*

Task Force deliberations were informed by several empirical findings:

- *Numbers of children and CHB families likely to benefit from DCD*. A review of ICU deaths at CHB for the years 2002-2004 indicated that, even if DCD is offered here, the number of eligible patients whose families choose DCD is likely to be only 1 or 2 per year.[ss] It was learned that, under UNOS policies, DCD organs donated by CHB patients would go to adults rather than children, because children have priority for organs of better quality.[tt]
- *Likelihood of staff conscientious objection to participating in DCD.* Feedback from CHB staff focus groups and other sources indicated that a proportion of ICU staff would have moral or religious objections to participating in DCD. In addition, four of six chaplains on the chaplaincy service reported "serious reservations" about participating.[uu] Given the differences of opinion within the staff focus groups and on the Task Force itself, it seemed likely the Hospital staff as a whole would be divided as well.
- *Differences among pediatric institutions in posture toward DCD.* The Task Force's survey of selected pediatric institutions indicated substantial differences in attitudes toward DCD, with a small majority of institutions surveyed adopting or leaning toward adopting a protocol and the others refusing to do so or deferring a decision.[vv] No other institution had convened a task force with the charge and institutional support of this one; several asked to be informed of the results of CHB's process.

With these considerations in mind, Task Force members debated the benefits and harms of DCD to the Hospital's various constituencies and Hospital's obligations to each of them. Members considered the effects that an affirmative or negative decision regarding DCD would be likely to have on the overall mission of the Hospital. These debates subsumed several subsidiary issues.

First, in its foundational conditions for DCD, the whole Task Force had agreed that DCD would not be acceptable at CHB if it would "alter the quality of care in the ICU." After many hours of discussion regarding the likely effects on ICU care, the group could not agree on the magnitude of the risk that that would happen. It is hoped that the detailed discussion in Part 2 above will

[ss] See Appendix B.
[tt] See Section II, Phase I, Report 2.1.
[uu] See Section II, Phase I, Report 2.3.
[vv] See Section II, Phase I, Report 3.3.

help Hospital leadership to make its own predictions, aided by the staff survey and other research recommended by the Task Force in Section V.

Otherwise, the issues broached were questions of fairness and issues of priority among stakeholders and among institutional values. These are matters that Hospital leadership is best suited to judge. The Task Force's reasoning about them may be summarized as follows.

3.1. WEIGHING OF BENEFITS AND HARMS TO THE HOSPITAL'S CORE CONSTITUENCIES

To Task Force members who supported DCD, the estimates regarding number of organ donors and age of recipients were not particularly relevant. Each patient and parent was to be treated as an individual rather than a number. These members focused instead on the following advantages they expected from having a protocol:

- *Organ donation could be exceptionally comforting* to those families who choose it. Some staff who had worked with such families around brain death had been moved by the depth of families' gratitude for the chance to donate. This view was supported by anecdotal reports from other pediatric institutions that DCD is greatly appreciated by families who choose it, although it can be difficult for staff.
- *Offering DCD would honor parents' preference and values.* It would support the Hospital's efforts to respond to the diversity of values held by our patients and families. In the view of many members, failing to give parents the choice would be unjustifiably paternalistic.
- *Offering DCD would be a way of affirming the importance of the life-saving potential of transplantation.* To some members, this is as central to the CHB mission as maintaining the current culture of our ICUs.

To Task Force members who had significant reservations about DCD, the unexpected findings regarding the small number of CHB patients likely to donate via DCD and the small likelihood that other children would receive the donated organs called into question the amount of overall benefit that adopting a protocol could confer on the populations that are central to the Hospital's mission. These members questioned the assumption that DCD would necessarily confer a real benefit on even the 1 or 2 families per year who chose it; rather, they thought some parents might regret the choice afterwards and others might find other equally comforting ways of memorializing their child. (It was noted that there is no experience with DCD in children under 10 in the New England region and little such experience nationally, so that there is little basis for predicting its effects.) They also worried about causing mistrust, distress or offense to the 1 or 2 families per year whose children would be eligible but who would refuse to discuss or accept organ donation.

In the view of these Task Force members, there was a substantial prospect of diminishing the quality of ICU care around the withdrawal of life sustaining treatment. Problems included the possibility of premature decisions to withdraw life support; threats to family welfare and family trust arising from the necessity to request donation immediately after discussions of withdrawing life support; and dilution of the child-focused ethos of the ICU due to requirements to screen most dying children for eligibility as an organ source and pressures on established guidelines for

medical management of dying patients. This prospect carried great weight both because of the numbers involved and because of the importance Task Force members attached to maintaining the child-protective ethos of the unit. In their view, DCD could contribute to an unacceptable slide down a "slippery slope," involving two unfortunate tendencies:

- treating some patients as instruments for the service of others, without the patient's first-person consent, and
- making it harder to maintain the traditional "bright lines" around euthanasia that help ensure the integrity of the end of life care CHB provides.

For some this was primarily a matter of right and wrong, involving showing respect for the dying child and minimizing conflicts of interest in clinical practice. For others, the numbers of patients affected for better or worse was also a factor. At most, DCD could benefit 1 or 2 CHB families and 2-4 adult kidney recipients each year. These members felt greater priority should be given to the far larger number of children who would die in our MSICU and CICU without being able to donate. There were 254 total deaths over the 3-year period reviewed, of which 233 were cardiac deaths.

While all members were concerned about maintaining standards in the ICU, supporters of DCD took the view that line-drawing and redrawing are difficult but necessary features of everyday practice and that CHB clinicians could manage DCD in the same principled and sensitive way that they manage other potential conflicts of interest.

3.2 OBLIGATION TO SUPPORT ORGAN TRANSPLANTATION

To most Task Force members, organ transplantation is an important component of the health care system in which we practice. We have seen its benefits for many of our patients. Most members believed that CHB, like other institutions and individuals, should generally aim to support transplantation as an element of the "common good."

The Task Force considered and rejected the idea that, as an institution that accepts organs from the national organ pool, CHB owes a duty of reciprocity to contribute organs in return. It was noted that donated organs are allocated to individual recipients, not to institutions, and that the idea of direct reciprocity entails an unacceptable way of looking at human organs -- as commodities for exchange rather than "gifts of life." Members also pointed out that any duty owed to the transplantation system is a duty owed by the institution as a whole, not by the children whose end of life care could be adversely affected by DCD. It was argued that there should be better ways for us to seek to do our share for organ donation. By way of comparison, it was noted that CHB is conservative in its standards for accepting live organ donation from adult strangers who wish to give a kidney to an unknown child. Our obligation not to harm a living patient is taken very seriously in that context. In the view of some members, the Hospital should be similarly conservative when the patient is a dying child.

3.3 OBLIGATION TO OFFER A SERVICE THAT CAN BENEFIT SOME FAMILIES

In a related debate, the Task Force discussed whether the institution has an obligation to offer a new service like DCD.

The Task Force acknowledged and agreed that DCD is a compassionate act for some parents dealing with their child's illness and death. From a clinician's standpoint, the fact that some families will want and benefit from a new service such as DCD is often sufficient reason to offer it. We aim to serve the particular needs of each of our patients and families, even when, as a matter of available resources, the needs of each patient and family may be in competition with the needs of others in our care. If offering an important new service to one patient reduces to some extent the quality of a different service available to another, we should do our best to accommodate both, as long as neither patient's care will fall below the professional standards to which we hold ourselves at CHB.

Nevertheless, some Task Force members pointed out that hospital communities may legitimately choose to pursue certain goals over others, based on their own priorities and mission. CHB generally places a high value on protecting vulnerable children and promoting treatment choices that are in a child's best interests, even at the cost of challenging parental prerogatives. The Hospital is not obligated to offer its patients even medically uncontroversial treatment options that are part of the standard of care, such as burn care or maternity care for our pediatric patients, even if we have longstanding relationships with these patients and they would like to receive their care at CHB. In some members' view, DCD is a controversial, non-therapeutic option, which the Hospital has still less obligation to provide.

Other members argued that, although there are services we do not offer, such as burn care and maternity care for our pediatric patients, these are services for which referral and transfer are feasible. It is less burdensome to refer or transfer patients to the Shriners Hospital for Children for burn care or to the Brigham & Women's Hospital for maternity care than to transfer an imminently dying child to another ICU for purpose of withdrawing life support and donating organs. In the view of these members, if our policy is not to offer DCD, this will be unfair to our families because it will keep them from having access to DCD anywhere. (This issue is discussed further in Subsection 3.5 below.)

A final observation was that Children's Hospital prides itself on offering family centered care and doing its best to align the care and interests of parents and children. In the view of some Task Force members, DCD places the interests of parents and children in conflict. There is a question whether it could be harmful to our family-centered culture, or incongruent with our practice style, to pursue a service that could require us to probe the role of parents as decision-makers for their children.

3.3.1 Can We Do it Well?

There is no doubt the introduction of a DCD program would involve considerable planning and oversight, and that the potential impact within the institution could be significant for staff in many areas, including physicians, nurses and allied health care professionals providing end of life support. The Task Force debated not only whether it was appropriate to incur the possible costs to staff and the institution for a small number of potential DCD donors per year, but also whether there would be sufficient numbers of DCD donors for staff to remain comfortable and experienced with the protocol.

The Task Force noted that CHB is at the cutting edge of medical care and research, and has demonstrated the institutional ability in the past to devote the resources and provide the staff to ensure important programs are successful, no matter how small. The Task Force agreed that DCD, if adopted, would be done well at CHB, but would require ongoing independent leadership and review, staff education, data collection and training.

3.4 PROTECTION FOR STAFF CONSCIENCE

At the end of Phase I of the Task Force process, all Task Force members agreed that no CHB staff members should be pressured or compelled to participate in DCD if they had moral or religious objections to participation. In order to reach consensus to continue pursuing DCD at the end of Phase I, the group established the following condition as one of its 8 necessary foundations for DCD:

#7 - Diversity in religious, cultural and personal values will be respected. Staff who object to DCD may avoid participation.

Without agreement on this condition, a substantial portion of the Task Force would have recommended against DCD at the end of Phase I. Consequently, this principle was not in contention during Phase II.

Apart from its centrality to the original consensus reached by the Task Force, the principle was supported by several reasons. Respect for staff's moral and religious values is an important policy at CHB. Willingness to participate in DCD was not a predictable or reasonable job requirement when current staff members were hired. DCD is not the standard of care for pediatric patients, and there are substantial differences of opinion within the profession as to its appropriateness for children. ICU staff are reasonably expected to participate in the Hospital's standard modes of withdrawing life support; however, we generally honor refusals to participate in procedures that are more morally controversial, though legal, such as the withdrawal of medically administered food and fluid. At present, DCD's moral status is closer to the latter than the former. In the future, if DCD wins broad acceptance here, the expectations for participation by newly hired staff may change.

The Task Force considered the likely practical effects of honoring this principle if CHB wished to implement DCD. These effects are relevant to a prediction of the positive and negative consequences of adopting a DCD protocol at the Hospital. Depending on the number of

objectors, it might not be feasible to go forward with DCD on a given shift. Objecting staff might be subject to resentment or reprisals from other staff members who are required to take over their assignments. If the substitute staff were enthusiastic supporters of DCD, the problem would be mitigated. It was also noted that, if supporters of DCD were not able to offer it to families for whom it would appear to be a benefit, this could cause them distress.

For all involved -- patients and families as well as staff -- a change of staffing at the time just before withdrawal of life support could be at cross-purposes with the important CHB value of maintaining continuity of care. One Task Force member who objected to DCD expressed anguish at the moral dilemma presented by this prospect: withdraw from the care of a patient and family with whom one has established a relationship, or take part in a protocol that one feels is injurious to the patient.

The overall effect of protecting staff conscience on the merits of offering DCD depends on the extent of conscientious objection among CHB staff, once they know the details of the protocol. For this reasons, the Task Force recommends that a staff survey be conducted before any decision is made to adopt a DCD protocol here.

3.5 ROLE OF CHB VIS-À-VIS OTHER PEDIATRIC HOSPITALS AND TRANSPLANT CENTERS

Differences in DCD policy among other hospitals raised two ethical questions for the Task Force. One had to do with the immediate impact on our local patients from the possible discrepancy in availability of DCD between CHB and some other Boston hospitals. The other question concerned our leadership role in the pediatric community nationally.

3.5.1 Fairness in Impact on Local Patients

Among local adult hospitals that have DCD protocols, others including Massachusetts General Hospital and New England Medical Center currently offer DCD for pediatric patients as well as adult patients. If CHB does not offer DCD, our families who wish to donate will be disadvantaged. Once a patient is dying in our ICU, transfer to one of these institutions for DCD could be possible, but the Task Force did not think it was feasible or humane or that families would choose it. Families who come to CHB for ICU care would be unable to donate their child's organs, whereas they could have done so if they had been admitted to a hospital across town instead.

To some Task Force members, this result would be unfair to our families. They would have no meaningful way of anticipating the difference in options offered at the two institutions and taking their child to the facility where organs could be donated. (Hospitals would be unlikely to advertise their donation policies.) Other members questioned the relative importance of donation when compared to other advantages of bringing a child to CHB, such as the assurance that the child's care is the first priority of caregivers. They also noted that, in the wider reference group of exclusively pediatric institutions, it would -- at least at present -- be more common and more predictable that a hospital might not offer DCD.

3.5.2 Leadership Role among Pediatric Institutions

The Task Force debated what would constitute leadership for CHB among pediatric institutions, in light of the growing trend toward offering DCD and the continuing reluctance or opposition of a few leading pediatric hospitals. It was noted that public and legislative support for organ donation is generally strong. Organ banks are well funded to advocate for increasing donation, both through public and hospital-based campaigns and through changes in JCAHO requirements and transplant center regulations. It appears that little if any specific consideration has been given to pediatric populations before these regulatory changes have been proposed.

In contrast to UNOS and its affiliates, pediatric hospitals have many other issues on their list of priorities. Few pediatric institutions can devote substantial resources to evaluating or implementing a practice like DCD, which affects relatively few families and whose ethical nuances may not be widely understood. Fewer still will find it feasible either to develop a protocol that makes DCD as responsive as possible to the needs of children and their families, or, if they have reservations about pediatric DCD, to question new requirements from JCAHO or the organ network.

Three roles for CHB were advocated:

- *Adoption*. To some Task Force members, the ideal role for CHB as a leading pediatric institution would consist in developing and implementing a high quality pediatric protocol and sharing it with others. Acknowledging the challenges of DCD, these supporters noted that CHB is often in the position of adopting innovative therapeutic approaches that require changes in our well-established methods of practice. DCD presents a similar challenge that we should embrace.

- *Delay.* To other members, leadership should take the form of questioning the trend for pediatric DCD and bringing the debate to the surface at the national level. Proponents of this view argued that it is unclear how DCD will, in practice, affect the core constituencies of CHB. If the effects are more damaging than beneficial, then premature implementation of DCD, particularly with children, could justifiably threaten public trust in both CHB and the transplantation system as a whole – trust that is based on the presumption that organ donation is voluntary and beneficial to donors. With these concerns in mind, CHB should defer implementation of a general DCD protocol until adequate research is available to assess the effects of pediatric DCD on end-of-life care for children and families.

- *Research.* Since DCD is an important initiative for the transplant community, some members suggested that CHB should take the initiative to further such research, by working with UNOS and with other pediatric institutions and transplant centers (*e.g.*, through NACHRI), especially those that already have protocols for children in place. The issues of greatest concern include (i) changes in the basis or timing of the decision to withdraw life support in children who become DCD candidates, (ii) changes in premortem patient management (including ability to stay faithful to

protocol guidelines under pressure) and (iii) long-term impact on families who choose to donate. Meanwhile, in this view, CHB should advocate a voluntary, "go-slow" approach to UNOS and JCAHO requirements as they pertain to children, until more is known about the effects of DCD on the care of children and their families. A limited time period could be established for revisiting the state of knowledge and the appropriate CHB policy.[ww]

[ww] See Appendix D and Section I, Background for DCD, Subsection 5.2.4.

SECTION V

RECOMMENDATIONS

1. **SHOULD CHILDREN'S HOSPITAL BOSTON ADOPT A PROTOCOL FOR DONATION AFTER CARDIAC DEATH?**

2. **CONTINGENCIES**

3. **STEPS TO BE TAKEN BEFORE FINAL ADOPTION OR IMPLEMENTATION OF THE PROTOCOL**

SECTION V

RECOMMENDATIONS

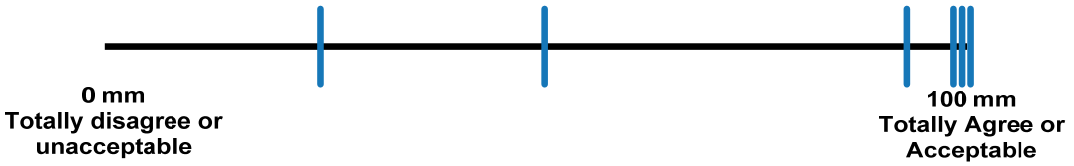
1. SHOULD CHILDREN'S HOSPITAL BOSTON ADOPT A PROTOCOL FOR DONATION AFTER CARDIAC DEATH?

THE TASK FORCE RECOMMENDS THAT THE HOSPITAL'S POLICY ON DCD BE BASED UPON THE FOLLOWING CONSIDERATIONS. THE DEGREE OF SUPPORT FOR EACH STATEMENT WITHIN THE TASK FORCE IS INDICATED, TOGETHER WITH THE SPECIFIC COMMENTS OF ALL MEMBERS IN RELATION TO EACH STATEMENT.

STATEMENT 1:

"Considering only the welfare and rights of DCD candidates and their families, DCD can be an acceptable choice for families if conducted under the proposed protocol."

Only for competent adults and mature or emancipated minors who have signed donor cards or entered their names in a donor registry.



[NB: 11 Task Force members affirmed DCD for all possible candidates and not only restricted to those on a donor registry; these members voted for statements 2 and 4 only.]

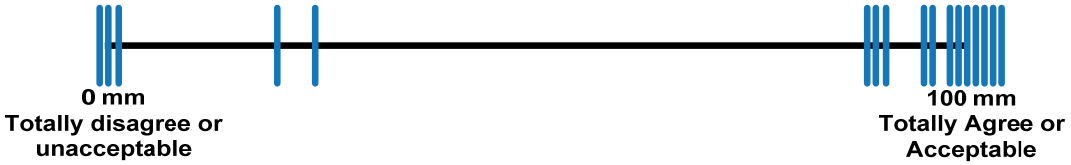
Please indicate if any of the 8 foundations have not been met with respect to this question.

- *Two conditions still have not been met: (1) satisfactory response to Foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with procedures to prevent any attempt at coercion (relates to Foundation #4). My vote is not zero because I think there's potential for progress on these conditions.*
- *Respect for patient autonomy. In keeping with current practice around family-centered care, patient-centered care. Foundation #7 as relates to families and patients. I agree this excludes other pediatric patients.*
- *Abstain—I certainly support it in these donors, but I would not limit it to this age category.*
- *As a pediatric institution CHB must take a leadership position in pediatric DCD.*

STATEMENT 2:

"Considering only the welfare and rights of DCD candidates and their families, DCD can be an acceptable choice for families if conducted under the proposed protocol."

For all possible candidates, including small children



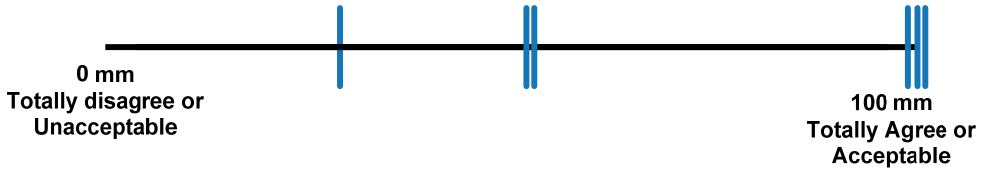
Please indicate if any of the 8 foundations have not been met with respect to this question.

- *Violates best interest standard*
- *Comfort level-challenging decision. Many factors to weigh.*
- *I believe that we give parents a lot of latitude to make major decisions about treatment options etc. even when children cannot give their consent/assent. So… if that's the felling who we believe has the best interest of the child in heart should be able to make decision about the DCD as well after the end of life of their child.*
- *I think that protocol is very thoughtful and well designed. It is crucial that this modality be available for families who desire it.*
- *The work, dedication, research, document etc. have resulted in a thorough presentation and summary of DCD regarding a pediatric health care facility. CHB is a leader in pediatric care and I hope that we will continue to be a leader in DCD, grow with it, change as DCD grows and be proactive in this field.*
- *I feel that parents can make this decision for minors. The decision to withdraw care is more weighty than DCD.*
- *I trust the clinical team will do the correct thing for the patients.*
- *Fails best interest standard and Kantian imperative.*
- *Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.*
- *DCD has risks, but it isn't so clearly harmful that no parent could justifiably choose it in the right circumstances. If we're only thinking of the one or two families a year who would choose it, we should respect their values and leave the choice with them, assuming all our protocol safeguards are in place.*
- *These children just are not dead yet. Their lives were cut short but they have the right to die in peace in their parent's arms in a safe place with nobody waiting behind the curtains to snatch their body away. These innocents should not be seen in pieces as possible kidneys or livers by those* who *profit from taking parts of their bodies. In life, young children are not altruistic so why would we assume they would be when near death?*
- *If offered – offer to all.*

STATEMENT 3:

"Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD protocol"

Only for competent adults and mature or emancipated minors who have signed donor cards or entered their names in a donor registry



[NB: 11 Task Force members affirmed DCD for all possible candidates and not only restricted to those on donor registry; these members voted for statements 2 and 4 only.]

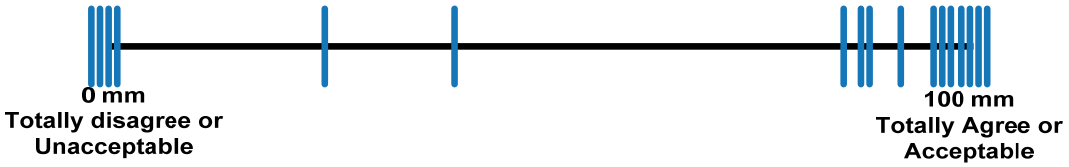
Please indicate if any of the 8 foundations have not been met with respect to this question.

- *"A" DCD protocol to advocate for the wishes of these patients is important and desirable. We should support the autonomy of our adult and mature patients. Our policy might be to refer competent adults and mature minors to adult hospitals that do DCD more often and have the expertise. e.g. obstetrics. I do not see DCD at CHB as consistent with our/a pediatric mission.*
- *Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.*
- *This policy – compared to offering DCD for all ages -- reduces the effects of DCD on overall ICU care, since we would only have to consider DCD (i.e., screen patient, involve organ bank, work in the shadow of conflicts of interest around end of life decisions) for this small and clearly defined sub-population. Other patients and families wouldn't be affected.*
- *Our mission is patient and family → the population is only part of our mission. Need to speak for the infant and child!*
- *Abstain-I certainly support it in these donors but I would not limit it to this age category.*
- *Please see statements—same reasons.*

STATEMENT 4:

"Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD protocol"

For all possible candidates, including small children and infants



Please indicate if any of the 8 foundations have not been met with respect to this question.

- *Violates best interest standard*
- *Given this DCD has emerged as appropriate option for organ donation it is imperative that Children's Hospital guide process with an appropriate model. My 95% only reflects that, as with any new venture, there are always concerns.*
- *After the work, I encourage CHB to be a leader locally and nationally. But let's do what we think is right—not news and what others hope to hear.*
- *I feel that parents can make this decision for minors. The decision to withdraw care is more weighty than DCD.*
- *Taking into account the mission of Children's Hospital Boston as a whole, the hospital should adopt a DCD proposal.*
- *Two conditions still have not been met: (1) satisfactory response to foundation # 1 assuring that WLS decisions are never made inappropriately (when the child still has a reasonable potential for a life of acceptable quality); 2) satisfactory resolution of the questions about conflict of interest between CHB and NEOB, with ironclad procedures to prevent any attempt at coercion (relates to foundation #4). My vote is not zero because I think there's potential for progress on these conditions.*
- *Acceptability depends largely on (1) whether the protocol can be followed as intended, especially under pressure from the OPO, (2) whether the mandatory DCD screening of all candidates for withdrawal of life support will adversely affect the child-protective ethos of our ICUs, and (3) whether there is truly enough potential benefit to justify the ethical quandaries (including the possibility of premature withdrawal of life support) resulting from conflicts of interest. The donor children can't benefit and they're our first priority. Even the benefit to families is not convincing, as there is no research (mainly anecdotes selected by the OPO) and regrets seem likely. Much of the support for DCD seems driven by outside pressures rather than by our usual standards of care. (Foundations 1 & 4 aren't met.)*
- *For some families this will clearly be a good thing to offer and provide. For many families, the involvement of NEOB and the inherent conflicts of interest created by any DCD protocol will diminish the quality of the end-of-life care we provide. No changes in the protocol can entirely mitigate this inherent problem. Adrienne's data suggest that the number of organs procured in this way will be small. From the perspective of NEOB, the primary benefit of our adopting a DCD protocol will not be the organs obtained, but the public relations benefit of having our*

prestigious pediatric hospital "on board." For me, the cost / benefit analysis of this tilts in the direction of not adopting the protocol. I do recognize, however, that this will deny an important opportunity for a small number of families for whom this would be desirable

STATEMENT 5:

"Recognizing the special concerns applicable to pediatric DCD, CHB should defer implementation of the DCD protocol until adequate research is available to assess the effects of pediatric DCD on the quality of end-of-life care for children and families, including the decision-making process for withdrawal of life sustaining treatment. In the interim, CHB should work with other pediatric institutions and transplant centers to further such research."

Comments from Task Force members regarding the above statement:

- *I feel like CHB should be the leader in this regard.*
- *CHB should take the lead in knowledge development in this area. We cannot wait for others to confirm our practice. We must confirm our own practice.*
- *We cannot do this type of research if we don't do this procedure. We can't let others to do the research for us.*
- *Hard to measure because I would not want CHB to wait but would hope CHB would be leader and share. I would want us to share and work with other pediatric institutions if asked but hope CHB would not wait for others if SLC with recommendation from DCD task force decides to go forward. CHB provides care that I believe is always aimed to be in the best interest of the child/patient and believe we will continue this practice—not changing for DCD. The foundations required for DCD I believe (hope?) would be implemented. Thank you for all the great work and inviting me to participate.*
- *I do not think this is appropriate justification for not moving forward with DCD. On the other hand, I would favor ongoing scrutiny and refinement. Furthermore, if our deliberations have highlighted gaps in end of life care, these should certainly be addressed in an appropriate forum.*
- *I do not believe we need to defer implementation of DCD protocol, but we should participate in ongoing research as we move forward.*
- *We have an obligation to provide leadership—we are being looked at by other organizations. We have the resources and the responsibility. Regardless of final decision, we need to be out in front, providing background re: this thoughtful process.*
- *Applaud more research. We should continue to be lively participants in this topic. More research will not necessarily make it ethically more acceptable.*
- *We need to study the validity of the decision to WLS itself as well as the context (free of coercion) in which the decision to pursue DCD is made.*
- *Whatever our policy, we should be able to defend it openly to the public, or we risk losing their trust in the hospital and in transplantation. We should support a meaningful evaluation of the effects of DCD, and make a decision on that basis.*
- *Am not sure that more "research" or work with other institutions at this time will move process as believe we have put maximum effort into examining in exquisite detail. The complex issues for patients, families and staff though; believe we should work with other institutions as we and they progress to address all the salient and sticky issues, and for sure, try to refine protocols for procedures, decision making, support to patients, families and staff.*

2. CONTINGENCIES

All affirmative votes on Statements 1 - 4 were contingent on the Hospital's adoption of the Protocol and Considerations for Implementation (Section III, Phase II, Report 2.1) and Informed Consent Guidelines (Section III, Phase II, Report 2.4) developed by the Task Force, as well as an institutional commitment to taking the steps outlined below.

3. STEPS TO BE TAKEN BEFORE FINAL ADOPTION OR IMPLEMENTATION OF THE PROTOCOL

Prior to a final decision regarding adoption of a DCD protocol, the Task Force recommends three further steps to assess the probable impact of DCD and involve the CHB community in decision-making regarding DCD. If a decision is made to go forward with DCD at the Hospital, the Task Force recommends a third step – an initiative to improve relationships between the New England Organ Bank and the staff of the CHB MSICU and CICU -- as a prerequisite for implementation.

3.1 Staff Survey

The advisability of adopting DCD depends in part on the likely impact on staff of both the successful implementation of a DCD protocol and the quality of ongoing care for patients and families. As indicated in the foundational criteria set by the Task Force, it is central to the acceptability of the protocol that no staff should be pressured to participate or sanctioned for declining to participate. On the basis of data from internal focus groups conducted by the Task Force in Spring 2005, later anecdotal responses of staff, and the division of opinion on DCD within the Task Force itself, it appears that some staff will embrace DCD as a service to families while others will object to participation.

If there is a sufficient number of staff objecting to participation in DCD, particularly in those areas directly involved with withdrawal of life support such as ICU medical and nursing staff and the chaplaincy service, it is likely that it will be necessary to change caregivers on short notice at a very stressful time for both family and staff. Widespread or deeply felt discomfort with DCD could impair staff morale within a unit and make it difficult to provide the kind of family-centered care that is usually offered at CHB when patients are dying. Staffing in the OR may be affected as well. On the other hand, a strong voluntary commitment to DCD as an important and helpful option for families could make DCD a positive experience for those who choose to be involved. It is difficult to assess the impact of offering DCD without a precise understanding of the extent to which staff would be willing to participate.

General concerns of staff, for and against DCD, were brought to the surface in the non-confidential focus groups convened by the Task Force in early 2005. The information and case scenario presented to the internal focus groups in 2005 was based on a previously established and adult-based protocol written by the NEOB. The protocol developed by the Task Force has been written specifically for CHB and it may now be possible to gauge with more precision the acceptability of DCD to each staff member who might be asked to participate.

We recommend that staff likely to be involved in DCD be re-surveyed as to whether they would (i) willingly participate in DCD, (ii) participate but with some moral discomfort, or (iii) decline to participate at all. The survey should be preceded by education about DCD and the proposed protocol. In order to assure confidentiality, particularly for staff in small services, survey results should be shared on a limited basis as necessary for institutional decision-making. The Task Force recommends that the survey be conducted by an independent survey research organization, with help from the Task Force in developing the educational materials.

3.2. Community Review

In its 1997 report on DCD, the Institute of Medicine recommended that the adoption of DCD protocols be characterized by "complete … public openness" and that community representatives, including donor families and transplant recipients, be involved in the approval process. Among institutions subsequently surveyed by the IoM regarding their DCD adoption process, strategies for community representation and acceptance involved inclusion of public members on hospital ethics committees, community oversight committees and boards of trustees, as well as media outreach.

The DCD Task Force at Children's Hospital Boston has included a public representative and a parent representative among its seventeen members. If CHB leadership determines that it would be consistent with the Hospital's mission to adopt a protocol, it would be advisable to seek broader community review. If leadership leans toward declining to adopt a protocol at this time, community review of that decision might also be appropriate. The Task Force could be involved if desired.

3.3. Improvement in NEOB-ICU Relationships

It is apparent to the Task Force that the relationship between CHB intensive care staff and NEOB is suboptimal. NEOB has agreed that the approach to pediatric organ donation has complexities not present in an adult setting, and has affirmed that it will continue to work closely with clinicians in discussing and planning organ donation. There was an excellent working relationship between Task Force members and Kevin O'Connor, the NEOB Director who participated in protocol design with the Task Force. Nevertheless, on the floor of the MSICU and CICU, there have been concerns expressed by CHB staff about pressure or coercion for decision making (whether intentional or not) and interference with patient management on the part of other NEOB representatives. Problems are reported in relation to the Hospital's existing procedures for donation after brain death, and there is concern that these problems could be exacerbated in DCD, when the prospective donor is still alive. Federal regulations clearly support organ donation and the efforts of organ procurement organizations, including the reporting of impending deaths to an OPO for possible consideration of organ or tissue donation. Inherent conflicts between donor care and organ procurement must be managed satisfactorily if the foundational criteria for DCD are to be met.

To this end, the Task Force recommends that an improvement in the relationship between CHB and NEOB is a requisite for the implementation of the DCD protocol. A mutually supportive and productive relationship must be developed. While efforts to achieve this have been pursued and will continue between CHB ICU and NEOB staff, it is recommended this be coordinated through the executive leadership of both CHB and NEOB.

APPENDICES

Appendix A: Durall A, Laussen PC, Randolph A. Potential for Donation after Cardiac Death in a Children's Hospital. *Pediatrics* 2007.

Appendix B: CMS Interpretation of Regulations Pertaining to Organ Donations

Appendix C: Response from CHB to the NEOB Memorandum of Understanding

Appendix D: Comments submitted by Co-chairs of the Task Force during the Open Comment Period for the Proposed OPTN By-Law Requiring all Transplant Hospitals to Implement Protocols for Organ Donation after Cardiac Death

Appendix E: Response Letter from Pediatric Transplant Committee of UNOS

Appendix F: Curley MAQ, Harrison CH, Craig N, Lillehei CW, Micheli A, Laussen PC. Pediatric Staff Perspectives on Organ Donation after Cardiac Death in Children. *Pediatric Critical Care Medicine* 2007 (accepted for publication).

Appendix G: Survey Questions to Free-Standing Pediatric Hospitals regarding Practices and Policies for DCD.

Appendix H: Subcommittee on Family Views and Ethics of Proxy Consent: Phase II Report and Bibliography

Appendix I: Task Force Members: Biographical Sketches

APPENDIX A

Potential for Donation after Cardiac Death in a Children's Hospital

Amy L. Durall, MD[1]
Peter C. Laussen, MBBS[2]
Adrienne G. Randolph, MD, MSc[1]

Division of Critical Care, Department of Anesthesia, Perioperative and Pain Medicine[1] and Department of Cardiology[2], Children's Hospital, Boston, and Department of Anaesthesia, Harvard Medical School

ABSTRACT

Objective: A task force was convened to decide whether a donation after cardiac death (DCD) policy should be implemented at Children's Hospital, Boston. As part of this process, we sought to determine the number of potential kidney DCD donors in our pediatric intensive care units.
Methods: We examined all 254 deaths in the Medical/Surgical Intensive Care Unit (MSICU) and the Cardiac Intensive Care Unit (CICU) from 2002-2004 and identified potential DCD donors. Inclusion criteria were age ≥ 3 months of age, mechanical ventilation, and creatinine ≤ 1.5 mg/dl. Exclusion criteria were HIV infection, malignancy other than primary brain tumor or non-melanoma skin cancer, evidence of ongoing infection, death despite resuscitation attempts, and brain death.
Results: Twenty-one of the 254 deaths (8.3%) met criteria for brain death and 233 patients (91.7%) did not. Of the 116 patients over 3 months of age for whom life support was withdrawn, 92 (79.3%) were not suitable for kidney DCD. Of the 24 children identified as potentially eligible for DCD, 14 (58.3%) died within 1 hour of withdrawal of support and could have proceeded with DCD. In the other 10 children (41.7%), donation would have been aborted due to prolonged time to death.
Conclusions: 5.5% of all patients who died in our intensive care units would have been potential candidates for DCD. Assuming the rates of parental consent are similar to that of our heart-beating organ donors (47%), a DCD protocol could have potentially yielded 7 additional organ donors and 14 additional kidneys over this 3 year period.

For full manuscript see: Durall A, Laussen PC, Randolph A. Potential for Donation after Cardiac Death in a Children's Hospital. *Pediatrics* 2007, 119:219-224.

APPENDIX B

Center for Medicare & Medicaid Services (CMS) Interpretation of Regulations Pertaining to Organ Donations

§482.45 Condition of Participation: Organ, Tissue and Eye Procurement

---

A-0370

§482.45(a) Standard: Organ Procurement Responsibilities

The hospital must have and implement written protocols that:

Interpretive Guidelines §482.45(a)

The hospital must have written policies and procedures to address its organ procurement responsibilities.

A-0371

§482.45(a)(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

Interpretive Guidelines §482.45(a)(1)

The hospital must have a written agreement with an Organ Procurement Organization (OPO), designated under 42 CFR Part 486. At a minimum, the written agreement must address the following:

- The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital;
- Includes a definition of "imminent death";

- Includes a definition of "timely notification";

- Addresses the OPO's responsibility to determine medical suitability for organ donation;

- Specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s);

- Provides for notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement;

- Ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the hospital;

- Permits the OPO, tissue bank, and eye bank access to the hospital's death record information according to a designated schedule, *e.g.*, monthly or quarterly;

- Includes that the hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery; and

- The interventions the hospital will utilize to maintain potential organ donor patients so that the patient organs remain viable.

Hospitals must notify the OPO of every death or imminent death in the hospital. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital's medical staff and governing body, to define "imminent death." The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the hospital's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff.

The definition for "imminent death" might include a patient with severe, acute brain injury who:

- Requires mechanical ventilation;

- Is in an intensive care unit (ICU) or emergency department; **AND**

- Exhibits clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold; **or**

- MD/DOs are evaluating a diagnosis of brain death; **or**

- An MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

Hospitals and their OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glascow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital's OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the particular circumstances in each hospital.

Hospitals may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital's responsibility to notify the OPO.

"**Timely notification**" means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within 1 hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor. Even if the hospital does not consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour); **AND**

- Prior to the withdrawal of any life sustaining therapies (*i.e.*, medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor. Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be

viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

Survey Procedures §482.45(a)(1)

- Review the hospital's written agreement with the OPO to verify that it addresses all required information.

- Verify that the hospital's governing body has approved the hospital's organ procurement policies.

- Review a sample of death records to verify that the hospital has implemented its organ procurement policies.

- Interview the staff to verify that they are aware of the hospital's policies and procedures for organ, tissue and eye procurement.

- Verify that the organ, tissue and eye donation program is integrated into the hospital's QAPI program.

A-0372

§482.45(a)(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

Interpretative Guidelines §482.45(a)(2)

The hospital must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors.

It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an

agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes."

The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue and eye, or by a separate agreement with another tissue and/or eye bank outside the OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.

Survey Procedures §482.45(a)(2)

Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. The agreement should also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation, unless the hospital has an alternative agreement with a different tissue and/or eye bank.

A-0373

§482.45(a)(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate.

Interpretive Guidelines §482.45(a)(3)

It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.

Survey Procedures §482.45(a)(3)

- Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate.

- Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate?

A-0374

§482.45(a)(3) continued
The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an

individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

Interpretive Guidelines §482.45(a)(3)

The individual designated by the hospital to initiate the request to a family must be an organ procurement representative, an **organizational representative of a tissue or eye bank**, or a designated requestor. Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process.

The individual designated by the hospital to initiate the request to the family must be an OPO, tissue bank, or eye bank representative or a designated requestor. A "**designated requestor**" is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community.

Ideally, the OPO and the hospital will decide together how and by whom the family will be approached. If possible, the OPO representative and a designated requestor should approach the family together.

The hospital must ensure that any "designated requestor" for organs, tissues or eyes has completed a training course either offered or approved by the OPO, which addresses methodology for approaching potential donor families.

Survey Procedures §482.45(a)(3)

- Review training schedules and personnel files to verify that all designated requestors have completed the required training.

- How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate?

A-0375

§482.45(a)(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

Interpretive Guidelines §482.45(a)(4)

Using discretion does not mean a judgment can be made by the hospital that certain families should not be approached about donation. Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family.

All potential donor families must be approached and informed of their donation rights.

Survey Procedures §482.45(a)(4)

- Interview a hospital-designated requestor regarding approaches to donation requests.
- Review the designated requestor training program to verify that it addresses the use of discretion.
- Review the hospital's complaint file for any relevant complaints.

A-0376

§482.45(a)(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues;

Interpretive Guidelines §482.45(a)(5)

Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process;
- Importance of using discretion and sensitivity when approaching families;
- Role of the designated requestor;
- Transplantation and donation, including pediatrics, if appropriate;
- Quality improvement activities; and
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's QAPI program.

Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.

Survey Procedures §482.45(a)(5)

- Review in-service training schedules and attendance sheets.

- How does the hospital ensure that all appropriate staff has attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank?

A-0377

§482.45(a)(5) continued
Reviewing death records to improve identification of potential donors; and

Interpretive Guidelines §482.45(a)(5)

Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff performance might be improved. The policies must address how patient confidentiality will be maintained during the review process.

Survey Procedures §482.45(a)(5)

- Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.

- Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.

- Validate how often the reviews are to occur. Review the protocols that are in place to guide record reviews and analysis.

- Determine how confidentiality is ensured.

A-0378

§482.45(a)(5) continued
Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

Interpretive Guidelines §482.45(a)(5)

The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs. The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

Survey Procedures §482.45(a)(5)

- Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

- Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.

APPENDIX C

Children's Hospital Boston
President and Chief Executive Officer
Department of Urology

HARVARD MEDICAL SCHOOL
Professor of Surgery
The Robert and Dana Smith Professor

James Mandell, M.D.
Children's Hospital Boston
300 Longwood Avenue
Boston, Massachusetts 02115
phone 617-355-8555 | *fax* 617-730-0630
james.mandell@childrens.harvard.edu

Memorandum of Understanding between Children's Hospital Boston and New England Organ Bank, Inc.

The memorandum of understanding distributed by the New England Organ Bank, sets forth requirements for both Children's Hospital Boston and NEOB to facilitate the donation of organs, tissues and eyes. It is based on the interpretation of regulations established by the Center for Medicare and Medicaid Services (*Regulation 482.45 "Condition of participation: organ tissue and eye procurement"*).

The language and interpretation enclosed in the MOU pertains to all organ and tissue donation. The MOU is inclusive for organ donation from brain dead donors as well donation after cardiac death, and there are no specific considerations as to the unique nature of organ donation for children. The MOU has been reviewed by the Chief Executive Officer, director of the Pediatric Transplant Center at Children's Hospital, the directors of the Multidisciplinary and Cardiac intensive care units, and senior counsel. It has been signed as requested to comply with CMS regulations, however because of the unique aspects of organ donation in pediatric patients, there are important aspects in the MOU we wish to emphasize:

1. CHB is committed to the ongoing development and expansion of all organ donation and transplantation initiatives, and recognizes that close collaboration with NEOB, is an integral component to the success.

2. Specific policies, guidelines and protocols for organ and tissue donation and transplantation between Children's Hospital Boston and the New England Organ Bank, Inc., need to be written and implemented. Within this written agreement, the requirements and collaboration between CHB with the NEOB will be outlined. These policies and guidelines should include practices that differentiate the unique nature of pediatric transplantation, and establish collaborative practices between CHB and NEOB. In addition, the definitions of "timely notification" and "imminent death" will also be defined for pediatric patients.

3. A mechanism for monitoring outcome and compliance with the MOU needs to be established through the director of the Pediatric Transplant Center at CHB. This will also include the development of in-service education programs on organ, tissue and eye donation for CHB staff.

4. NEOB provide formal training of selected CHB staff to become approved requestors for organ donation.

Signed: Dated: 11/22/2006

James Mandell, MD
President & Chief Executive Officer

APPENDIX D

RE: Proposed OPTN By-Law Requiring all Transplant Hospitals to Implement Protocols for Organ Donation after Cardiac Death (DCD)

As co-chairs of a hospital-wide Task Force on Donation after Cardiac Death (DCD) at Children's Hospital Boston, we wish to submit a comment regarding the proposed OPTN by-law change that would require all transplant hospitals to implement DCD protocols as of 1/1/2007. Specifically, we urge that the requirement be delayed for *pediatric* institutions, and that a national consensus conference on pediatric DCD be convened in the near future, at which time the by-law can be reconsidered on the basis of evidence and opinion gathered at the conference.

We share in the OPTN's commitment to developing a well-functioning, ethical organ donation system nationally. We are, however, concerned that the currently proposed by-law does not address issues that are specific to those institutions caring for a pediatric population. As children are such a vulnerable population, we believe that special consideration is needed. It is important to note that our concerns relate only to the *requirement* that DCD be implemented. Pediatric institutions could still choose to offer DCD, as appropriate to their institutions and local communities, and greater technical assistance could become available as best practices are identified.

As the largest pediatric research and training institution in the United States, with an active transplant program including procurement of organs after brain death, our institution is committed to excellence in pediatric transplantation. We are bringing that same commitment to excellence to the issue of donation after cardiac death. Thus, we have instituted a multidisciplinary Task Force to address this issue. This Task Force was appointed by senior leadership and includes representation from transplantation, intensive care, neurology and palliative care physicians, intensive care and operating room nursing, respiratory therapy, clinical ethics, clergy, social work and family groups.

This Task Force has undertaken an exhaustive review of DCD, investing many hours in fact-finding, protocol design and deliberation about the clinical and ethical merits for pediatric patients and families in the context of the mission of our hospital. We have developed a protocol for DCD and our Task Force recommendations are currently under consideration by senior clinical leadership. We have been carefully following the recommendations for developing a DCD policy as outlined in the Institute of Medicine reports in 1997 and 2000, and we are concerned that the same rigor has not been applied to the formulation of the proposed OPTN by-law change.

Among the reasons for our suggestions regarding the by-law are the following:

1. DCD continues to be particularly controversial in pediatrics. The reasons include:

    - great vulnerability and special needs of children, who may be affected differently than adults by premortem interventions involved in DCD

- greater uncertainty regarding neurological prognosis after severe brain injury in children than adults, leading to greater risk of premature decisions to withdraw life support

- dearth of research on DCD in children, including appropriate timing of the declaration of death and impact of DCD on families, care providers and public

2. Most national initiatives with regard to DCD have omitted direct consideration of pediatric issues. This includes the IoM reports and the 2006 UNOS national consensus conference on DCD.

3. To delay DCD implementation in pediatric hospitals would not be a significant disadvantage to children:

    - There is little if any direct benefit to children in DCD. Under UNOS policies, DCD kidneys generally go to adults rather than children, because children have priority for organs of better quality.

    - With adult donors, it is often argued that allowing organ donation benefits donors by effectuating their desire to donate. This argument is not applicable to most minors, who would not be expected to be altruistic and who do not have the legal capacity to choose donation for themselves.

4. A delay would have little effect on the overall organ pool, regardless of recipient age. The number of children able to donate successfully under DCD protocols is likely to be very limited. A peer-reviewed study of ICU deaths at our hospital, analyzing the 254 deaths in our Medical/Surgical Intensive Care Unit and Cardiac Intensive Care Unit during 2002-2004, found that implementation of a DCD protocol would likely have yielded only 7 additional organ donors and 14 additional kidneys over this 3-year period.

5. If approved by the OPTN Board in mid-December and made effective on January 1, 2007, the proposed OPTN by-law would give institutions only two weeks to comply. This time frame would circumvent important recommendations made by the Institute of Medicine in its 1997 and 2000 reports on DCD (then referred to as NHBD), including those reproduced in the attachment to this letter. These recommendations emphasize the importance of:

    - public input and transparency in protocol development and implementation
    - local approval for protocol adoption
    - voluntary consensus-building as the foundation for acceptance of DCD
    - research on the impact of DCD on families, care providers and the public

The unilateral approach suggested by the by-law change seems in contrast both to the deliberative process recommended by the IoM and the collaborative process suggested by JCAHO. Unless sufficient time is allowed for this kind of process to be followed by pediatric institutions, the welfare of our patients and families and the public credibility of our hospitals and the organ transplantation network could be in jeopardy.

We believe that further dialogue and open discussion are needed, and we would welcome an opportunity to meet with OPTN leadership or the pediatric subcommittee to discuss deferral of the by-law change, along with the convening of a pediatric DCD consensus conference and initiation of relevant research on DCD in children. Although we are writing as chairs of our DCD task force, Children's Hospital Boston as an institution is willing to commit time, personnel, and any desired leadership to the development of the consensus group.

Sincerely yours,

Charlotte H. Harrison, JD MPH MTS
Clinical Ethicist

Peter Laussen, MB BS
Chief, Division of Cardiac Intensive Care

SELECTED RECOMMENDATIONS FROM THE INSTITUTE OF MEDICINE RELATING TO THE PROCESS OF ADOPTING DCD/NHBD PROTOCOLS

Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement (1997), p4

"Recommendations for National Policy":

Recommendation 1:. Written, locally approved NHBD protocols.
Recommendation 2: Public openness of NHBD protocols.

> *"Protocols should be open, public documents, and given the ethical and medical complexity of NHBDs, organ procurement should be carried out only after advance thought and planning that has been reduced to a written protocol developed with public input (including the views of patient and donor families) and approved by appropriate local oversight bodies."*

Recommendation 5: "Efforts to develop voluntary consensus on non-heart-beating donation practices and protocols should be continued."

Recommendation 7: "Data collection and research should be undertaken to evaluate the impact of non-heart-beating donation on families, care providers, and the public."

APPENDIX E

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Since 1984   sharing organs, sharing data, sharing life

700 North 4th Street, Richmond, VA 23219
P.O. Box 2484, Richmond, VA 23218
tel: 804-782-4800
fax: 804-782-4816
www.unos.org

Walter Graham, Executive Director

December 7, 2006

Peter C. Laussen, MBBS
Chief, Division of Cardiac Intensive Care
Cardiac ICU Office

Charlotte H. Harrison, JD, MPH, MTS
Clinical Ethicist
Office of Ethics

Children's Hospital of Boston
300 Longwood Avenue
Boston, Massachusetts 02115

Dear Dr. Laussen and Ms. Harrison:

Thank you for your letter of concern regarding the proposed Donation after Cardiac Death proposal to be considered by the Board of Directors during its upcoming December 13-14, 2006, meeting. A blinded copy of your letter and accompanying documentation was shared with the Pediatric Transplantation Committee as well as representatives from the OPO and Membership and Professional Standards Committees, which developed this proposal, during the Pediatric Committee's November 9, 1006 meeting. I have enclosed an excerpt from the report on this meeting that outlines discussion related to the upcoming DCD protocol requirements and the concerns raised in your letter. Dr. Bill Harmon also shared comments specific to your center's work on developing such a protocol.

The Committee agrees that implementing a DCD protocol may be more difficult for pediatric hospitals. Consensus statements, such as that from the SCCM, frequently referenced by centers working to develop plans are not based on pediatric medicine, as no best practice models for DCD have been developed for children at this time. Members recognize it is essential for the pediatric intensivist community to endorse this practice for such protocols to be successfully adopted by pediatric hospitals. As you may know, Dr. Sue McDiarmid, President of the Board of Directors, is working with Organ Transplantation Breakthrough Collaborative Faculty to plan a Spring 2007 Pediatric Summit where this issue will certainly be a focal point, including a large number of pediatric intensivists who will comprise an essential audience. Dr. McDiarmid envisions this as an opportunity to develop best practices for pediatric donor improvement in general and DCD in particular. The Pediatric Committee believes that this will further and constructively support the JCAHO and OPTN requirements for DCD protocols in all hospitals, and hopes that you will be able to participate in this event. I will be happy to share detail with you as they become available as I value your input in this process.

In the interim, I will address the Pediatric Committee's concerns to the Board of Directors during its December 13-14, 2006, meeting. While this Committee reinforces its support of the DCD protocol initiative, it requests the Board and the Membership and Professional Standards Committee recognize the unique challenges faced by pediatric hospitals in establishing these protocols. I will request that enforcement of the policy for transplant hospitals treating primarily pediatric patients be deferred as long as a hospital demonstrates it has a plan and a specific timeline for putting a pediatric DCD protocol into place.

Again, I thank you for your letter and the feedback submitted regarding this public comment proposal. Please let me know if you have any additional questions or concerns.

Regards,

Stuart C. Sweet, M.D., PhD
Chair, OPTN/UNOS Pediatric Transplantation Committee

SCS/shc

cc: Charles Alexander, RN, MSN, Chair, OPO Committee
Jeffrey Punch, M.D., Membership and Professional Standards Committee
Sue V. McDiarmid, M.B., Ch.B., President, Board of Directors

Enclosure

APPENDIX F

Pediatric Staff Perspectives on Organ Donation after Cardiac Death in Children

Martha A.Q. Curley, RN, PhD, FAAN, Charlotte H. Harrison, JD, MPH, MTS, Nancy Craig, RRT, Craig W. Lillehei, MD, FAAP, FACS, Anne Micheli, RN, MS, Peter C. Laussen, MBBS

Author Affiliations: Critical Care and Cardiovascular Program (MAQC); Office of Ethics (CH); Department of Respiratory care (NC); Department of Surgery (CL) Perioperative Nursing (AM); and the Cardiovascular Intensive Care Unit (PL); Children's Hospital Boston, USA

ABSTRACT

Objectives. The aims of this project were to describe whether or not pediatric clinical staff believe that a donation after cardiac death program could be consistent with the mission and core values of a children's hospital and to identify specific considerations that staff would consider essential to determining the acceptability of such a program.

Methods. Qualitative study in which data were gathered from pediatric clinical staff during eight focus groups conducted in a children's hospital from March-April 2005.

Measurements and Main Results. Eighty-eight staff members participated. Six major themes emerged from qualitative analysis of the data: 1) identifying children who could be candidates for donation after cardiac death; 2) considering the best interests of the dying child; 3) approaching parents about donation after cardiac death; 4) preparing parents for their child's donation after cardiac death; 5) the need to do donation after cardiac death well; and 6) maintaining the integrity of a donation after cardiac death program. Themes were used to construct a conceptual framework describing a model pediatric donation after cardiac death program. Pediatric staff voiced numerous concerns. However, they identified "making it happen for families" who voice a desire to participate in organ donation as the primary reason for program adoption.

Conclusions. This study provides a framework for understanding pediatric staff perspectives on donation after cardiac death programs in children. Results suggest several possible elements that may be helpful in framing interdisciplinary dialogue and informing institutional practices in the design of a pediatric donation after cardiac death program.

APPENDIX G

Does your hospital permit DCD for pediatric patients?

1. **IF YES, ASK THE FOLLOWING:**
    a. Do you use a protocol?
    b. Was your protocol developed:
        - by the hospital?
        - by the OPO
        - other…
    c. Does your protocol permit any non-medically indicated procedures before death (*e.g.*, administration of heparin, placement of vascular cannulae, etc.)
    d. Does your protocol include specific guidance for end-of-life care, including administration of sedatives and analgesics?
    e. Do you use a protocol developed specifically for pediatric patients?
        - If yes, in what ways does the pediatric protocol differ from the protocol you use for adults?
    f. Could we have a copy of your adult and pediatric protocols?
    g. How many pediatric patients have been DCD donors? Over what time frame?
    h. In general, how has the process been perceived by the hospital clinicians?
    i. Did anyone express discomfort or refuse to participate? (What seemed to be troubling them? How did the hospital deal with those responses? Is there anyone on staff who still refuses to participate?)
    j. Has there been any media coverage or response from the community? Can you recall any anecdotes about cases that went particularly well or cases that were problematic?
    k. Did the institution do anything to consult parents, religious leaders, or other community members before the policy was made? Was there any action to inform the public after the decision was made?

- If yes, is there someone our hospital parent coordinator or chaplain could contact to hear about that experience?

2. **IF NO, ASK THE FOLLOWING:**
    a. Does your hospital permit DCD for adult patients?
        - If yes, why hasn't the practice been extended to pediatric patients?
        - If no, has your hospital considered developing a DCD policy?
    b. If your hospital has considered developing a policy, what are the main reasons why a policy has not been adopted?

APPENDIX H

SUBCOMMITTEE ON FAMILY VIEWS AND ETHICS OF PROXY CONSENT

PHASE II REPORT

Our subcommittee offers our ethics work from the Fall as one basis for evaluating the draft protocol, from the perspective of the dying child and families (those offered DCD and others in the ICU). The timing-of-death subcommittee report and draft protocol address some of these concerns; many questions are still open.

Attached for more background are the following:

- Summary of ethical frameworks (below)
- Table of possible harms and benefits to child and family (above, Section III, Part 2)
- Bibliography (below)

Our reasoning about the ethics of DCD is as follows:

Standard basis for treatment decisions in pediatrics is the "best interests of the child" (BI).

- Clinicians' primary obligation is to the patient.
- BI standard is an important safeguard given: (a) the vulnerability of children and the inability to advocate for themselves, (b) adult decision-makers may be unduly influenced by their own or others' conflicting interests.
- Parents are usually in the best position to decide what is in the child's best interests, subject to medical/societal limits.

The BI standard is hard to apply meaningfully to a DCD candidate:

- Benefits to the child are nonexistent or speculative, unless the child is a mature minor who has affirmatively chosen to be an organ donor (apply substituted judgment test).
- Child has a very limited/no meaningful experiential interest—scientific data indicates that there is near certainty that the child will not suffer or be conscious at the time in question.

If parents want to choose DCD for their child, can it be ethical for us to accept their choice and provide DCD—even though it cannot be said to be in our patient's best interests?

Yes, IF:

1. **Other ethical standards are met:**
   - "Rational parent" standard—If parents demonstrate "rational" decision making, they can choose DCD, acting within medical/societal limits.
   - "Clear benefit/harm" standard—Parents' choice should be accepted absent significant risk of serious preventable harm to the child.

- Balancing of benefits and harms is not out of proportion to tradeoffs in other intra-family contexts where we make exceptions to the BI standard (*e.g.*, sibling bone marrow donation, conjoined twins).

2. **Harms to the child are minimal to non-existent:**
   - No premature or unjustified decision to withdraw life support (WLS).
   - No physical harm
     - No invasive pre-mortem procedures (cannulation, placing of IV or CVL lines).
     - No pre-mortem RX that could hasten or actively cause death.
   - No suffering
     - Sedation is consistent with best non-DCD practice.
     - Parents may be present to comfort, hold and be companions to patient.
   - Respect for the dignity of the patient and family is maintained.
     - Dignity of the child is a matter of personal, religious and cultural values, best judged by the parents.
     - Continuity of care of patient and family is maintained by presence of ICU RN's, clergy and other known caregivers.
     - Needs for privacy, emotional and spiritual care (as defined by the family) are provided for in a culturally-sensitive manner.

3. **Parents believe that DCD will benefit their family more than other options available to them (serving our mission of family-centered care):**
   - Respects parents' right to choose an option that they perceive will benefit their family. Difficult to question or second-guess this perceived benefit.
   - This assumption is based on limited anecdotal evidence; research is very limited in this area.
   - Seems most likely to be true when parents initiate the discussion of organ donation—does this suggest a policy to offer DCD only upon request of parents?
   - How much more solace, if any, does DCD offer compared to other means of memorializing the child, tissue donation, etc.?
   - Need for our own research? Difficulties: who to survey; reliability; non-generalizable results, etc. At a minimum, we should track our own patient families' experience of the DCD decision.

4. **Key safeguards are in place to protect the integrity of the decision (family dignity), CHB's institutional culture and public trust:**

   - **Fully voluntary informed consent:**
     - Disclosure of all material information
       - Where organ would likely go—child, adult?
       - CHB interest in the organ, if any (see Conflict of Interest).
       - Other options for donation—such as tissue, autopsy, research—if parents are interested in donation.
       - Protocol steps/logistics—worked out in detail so that all aspects that could make a difference to the family are explained to parents.
     - Genuine voluntariness, avoiding even subtle coercion

        - Make clear that staff has no interest in parents' choice, mindful that parents may feel obligation of gratitude to help CHB or medical community.
        - Make clear that quality and consistency of patient care will be maintained, irrespective of choice
        - Parents must be able to change their minds at any time.

- **No staff conflicts of interest (COI):**
    - Bright line needed: decision to WLS must be prior to, separate and independent from decision to donate organs.
    - Can it be ethical for CHB to have the right of first refusal for DCD organs we retrieve?
        - Staff caring for dying child must not also be caring for prospective recipients. (Is it logically possible to ensure this is avoided?)
        - Would knowledge of a prospective recipient in the same unit create COI or an inappropriate attractive temptation?
        - Could we maintain confidentiality of donor and recipient?

- **No distortion of ICU care (for all patients):**
    - Staff will not have to consult NEOB or consider NEOB guidelines when they approach a family about WLS.
    - Collaborative assessment by the ICU staff and the NEOB as to suitability of patient for DCD (including chart review, etc.) will occur after and only if parents wish to consider organ and or tissue donation.

- **Protection for individual staff conscience:**
    - Will timing and other conditions be such that it is actually feasible for ICU staff and OR staff on any shift to refuse to participate, without others' resentment or reprisals?

- **Authoritative oversight and careful quality control:**
    - Oversight by individuals with sufficient authority and willingness to alter or stop the process if there are protocol deviations.
    - Need active involvement/monitoring in the moment—waiting for complaints afterwards will not be adequate (Affirmative check-offs? Informed consent colloquy? Multiple signatures?)

SUBCOMMITTEE ON FAMILY VIEWS AND ETHICS OF PROXY CONSENT

ETHICAL FRAMEWORKS[xx]

Background philosophical frameworks – two contrasting approaches

1. Utilitarian standard
   - Balance benefits/burdens to all—patient as well as society in general (cost of treatment, benefit of donated organ, etc.)—the greatest good to the greatest number; the end justifies the means.
   - Basis of cost-benefit analysis.
   - In its strict application, may be too inclusive of interests beyond the patient and family.

2. Kantian standard
   - Must treat humanity in any person as an end in itself and never solely as a means to an end.
   - Standard can be hard to apply on its own—does not tell us what to do if duties come in conflict with each other.
   - Kant was concerned with ethics among fully rational, autonomous beings – not children.
   - Other standards reflect what is appealing about this general value.
     - Basis of informed consent: treating patients/parents as an end requires transparency and shared decision-making.
     - A Kantian theory of justice (Rawls), in contrast to utilitarian theory, ensures that one individual's most basic welfare can't be traded off to benefit others.

Standards for decision making about treatment for children

3. "Substituted judgment" standard
   - Determine what the patient would have chosen under the circumstances based on most recent and reliable evidence of patient's values and desires. (Thomasma & Pellegrino)
   - Used for medical decision making on behalf of adults but not generally suitable to children that have not reached maturity.
   - May apply to older child with express wishes regarding organ donation.

4. "Best interest of the child" standard
   - "Patient-centered" principle—determine the net benefit for the child of each option, assigning different weights to reflect the relative importance of the various interests

[xx] Full citations to the sources noted in parentheses are available in the attached bibliography. There is one exception: "C. Mitchell" refers to a personal communication from Christine Mitchell to the Subcommittee.

they further or thwart; follow the course with the greatest net benefit to the child. (Buchanan & Brock)
- Important safeguard for vulnerable child, who cannot advocate for self.
- Child is so enmeshed in family that often we cannot meaningfully separate child's interests from family interests. (C. Mitchell)
- Some argue persuasively that this standard cannot apply to patients for whom "no return to an even minimal level of social or human functioning is possible" (President's Commission), who "permanently lack the capacity for consciousness and whose good can never matter to them" and who thus have no "experiential" or "morally considerable" interests. (Buchanan & Brock)
- Seems artificial to "create" or assign "benefits" for the unconscious, dying child; "any extrapolation of benefit to the child as a donor is a fiction." (subcommittee discussion).

5. "Rational parent" standard
   - Parents entitled to weigh benefits/burdens (including those to the family) as long as they can demonstrate "rational" decision making: "the ability to prioritize options for the child within the context of her own value system—coherent and consistent over time." (Cooper & Koch)
   - "Rational parents ought to be able to choose treatment for their child that may increase risk of harm . . . they should not be permitted to choose so low a level of care that it not only increases risk of harm but also guarantees that harm will occur." (Cooper & Koch)
   - Requires some medical/societal limit to inform what is "rational" or harmful.
   - Seems to allow consideration of various aspects of the different standards—captures the reality of this complex decision making process.

6. "Clear benefit" or "clear harm" standard
   - If clinicians believe a certain treatment would be "clearly beneficial" to the child and parents refuse it, this decision may be challenged on behalf of child; however, if clinicians see benefit as "ambiguous or uncertain," parents have right to choose or refuse the treatment. (widely accepted standard, generalized from President's Commission report *re* severely impaired newborns)
   - Parental refusal of treatment should be accepted unless it "places the child at significant risk of serious preventable harm." (Diekema)
   - Arguably, then, parents' choice of DCD (forgoing usual WLS protocol) should be accepted absent significant risk of serious preventable harm to the child. (subcommittee discussion)

Other intra-familial contexts in which we allow relaxation of the best interest standard

<u>Bone marrow donation by minor sibling</u>:
- Weigh likely success to recipient versus physical (generally considered minimal or unlikely) and psychological (evaluated by psychologist) burdens to donor (DFCI practice)

- Justifications: (i) psychological benefit to donor—sibling survival, family intact; (ii) we all come into the world with prima facie obligations within our family
- Best interest standard difficult to apply—which child's best interest? (Cooper & Koch)
- "The rational parent, upon measuring the risks to the younger [donor] child, might decide that the risks are negligible as compared with the potential benefit for the older [recipient] child." (Cooper & Koch)

Conjoined twins

- Twins share vital organs; only one can survive if surgery; both will die if no surgery—parents opted to try to save the healthier of the two.
- Medical decision based on "a utilitarian standard" rather than a 'best interest standard.'" (Cooper & Koch)
- "A rational parent could make this decision either way, weighing benefits and burdens to the children as well as to the family unit." (Cooper & Koch)

SUBCOMMITTEE ON FAMILY VIEWS AND ETHICS OF PROXY CONSENT

FAMILY SUBCOMMITTEE BIBLIOGRAPHY

FALL 2005

Anderson B, Hall B. Parent's Perceptions of Decision Making for Children. *Journal of Law, Medicine & Ethics*. 1995; 23:15-19

Angell M. The Doctor as Double Agent. *Kennedy Institute of Ethics Journal*. 1993; 3(3): 279-86

Baron CH. Medicine and Human Rights: Emerging Substantive Standards and Procedural Protections for Medical Decision-Making within the American Family. *Journal of Geriatric Psychiatry*. 1985; 18(2): 95-141

Berde C, Wolfe J. Pain, Anxiety, Distress, and Suffering: Interrelated but not Interchangeable. *The Journal of Pediatrics. 2003; Editorials: 361-63*

Blustein J. The Family in Medical Decision-Making. *Hastings Center Report*. May/June 1993; 6-13

Brock DW. What is the Moral Authority of Family Members to Act as Surrogates for Incompetent Patients? *The Milbank Quarterly. 1996; 74(4): 599-619*

Brody H. Introductory Guest Editorial. *Theoretical Medicine*. 1987; 8:253-57

Browett P, Palmer S. Legal Barriers Might Have Catastrophic Effects. *BMJ*. 1995; 312:240-3

Buchanan AE, Brock DW. *Deciding for Others: The Ethics of Surrogate Decision Making.* Cambridge University Press. 1985; 123-133, 138-145,190-196, 234-237,394-395,398-399,402-407

Burger AM, et al. Factors Influencing Ethical Decision Making in the Home Setting. *Home Healthcare Nurse*. 10(2): 16-20

Carlson EA, Sampson MC, Sroufe AL. Implications of Attachment Theory and Research for Development-Behavioral Pediatrics. *J Dev Behav Pediatr*. October 2003; 24(5): 364-379

Committee on Bioethics. Appropriate Boundaries in the Pediatrician-Family-Patient Relationship. *Pediatrics*. August 1999; 104(2): 334-36

Conto, N; Larson, J; Scofield. S; Sourkes, B; Cohen, H. Family Perspectives on the Quality of Pediatric Palliative Care. *Pediatrics & Adolescent Medicine.* 2002; 156:14-19

Cooper R, Koch KA. Neonatal and Pediatric Critical Care. *Critical Care Clinics*. January 1996; 12(1): 149-164

Council on Ethical and Judicial Affairs. *Code of Medical Ethics: Current Options with Annotations.* American Medical Assoc. 1996/97; 34-36

Coulton CJ. Research in Patient and Family Decision Making Regarding Life Sustaining and Long Term Care. *Social Work in Healthcare. 1990; 15(1): 63-79*

Craig H, Duncan J, Wolfe J. Caring for the Child With Cancer at the Close of Life: "There are People Who Make It, and I'm Hoping I'm one of Them". *JAMA.* November 2004; 292(17): 2141-2149

Delany L. Protecting Children from Forced Altruism: the Legal Approach. *BMJ*. 1995; 312:240-243

Diekema DS. Parental Refusals of Medical Treatment: The Harm Principle as Threshold For State Intervention. *Theoretical Medicine.* 2004; 25:243-264.

Dwyer J, Vig E. Rethinking Transplantation Between Siblings. *Hastings Center Report.* September-October 1995; 7-12

Emanuel EJ, Emanuel LL. Proxy Decision Making for Incompetent Patients. *JAMA*. 1992; 267(15): 2067-71

Ethics. Helping Patients and Families Make Life-Sustaining Treatment Decisions. *Aorn Journal.* June 1984; 39(7): 1128-33

Family Interests. Standards or Rules for Decision-Making. (Slide Presentation) Page 1-3; How should parents decide for their children? – the role of family-centered interests.

Fox R, Swazey J. Leaving the Field. In Caplan AL, Coelho DH, eds. *The Ethics of Organ Transplants: The Current Debate*. Prometheus Books. 1998.

Gothelf D, et al. Death Concepts in Suicidal Adolescents. *J Am Acad Adolesc Psychiatry*. December 1998; 37(12): 1279-1286

Hardart GE. Including the Family's Interests in Medical Decision Making in Pediatrics. *The Journal of Clinical Ethics*. Summer 2000; 11(2): 64-168

Hardart GE, Truog RD. Attitudes and Preferences of Intensivists Regarding the Role of Family Interest in Medical Decision-Making for Incompetent Patients. *Crit Care Med*. 2003; 31(7):1895-1900

Hardart GE, Truog RD. Practicing Physicians and the Role of the Family in Surrogate Medical Decision-making. *(Prepublication Draft)* p1-25

Hardwig J. The Problem of Proxies with Interests of Their Own: Toward a Better Theory of Proxy Decisions. *The Journal of Clinical Ethics*. Spring 1993; 4(1): 20-27

Hardwig J. What About the Family? *Hastings Center Report*. March/April 1990; 5-10

Healey JM. Deciding for the Incompetent Patient: The Role of Family Members. *Law, Medicine and Public Policy.* 1984; 48(7): 477

Jamieson DRS, Teasdale E, Willison HJ. False Localizing Signs in the Spinal Cord. *BMJ*. 1995; 312:240-3

Kane JR, Primomo M. Alleviating the Suffering of Seriously Ill Children. *American Journal of Hospice & Palliative Care.* May/June 2001; 18(7): 161-169

Kaplan, B; Griffin, RM. Parents'/Guardians'Views on Donation After Cardiac Death. *Crit Care Med.32(12): Suppl A89* (abstract to Poster Presentation: Ethics/End-of-Life/Compassionate Care Pediatrics).

Kapp MB. Family Decision Making For Nursing Home Residents: Legal Mechanisms and Ethical Underpinnings. *Theoretical Medicine*. October 1987; 8(3): 259-73

Keenan, S.; Hoffmaster, B.; Rutledge, F.; Eberhard, J.; Chen, L.; Sibbald, W. Attitudes Regarding Organ Donation from Non-Heart Beating Donors. *Journal of Critical Care. 2002;* 17(1):29-38

Kolata, G. Controversy erupts over organ removals. *New York Times* 4/13/97.

Kom, AA; Ackerson, L; Lo B. How Pediatricians Counsel Parents When No "Best-Choice" Management Exists. *Arch Pediatr Med*. 2004;158:436-41

Kopelman LM. Children and Bioethics: Uses and Abuses of the Best-Interests Standard. *The Journal of Medicine and Philosophy.* 1997; 22:213-217

Kopelman LM. What Conditions Justify Risky Nontherapeutic or "No Benefit" Pediatric Studies: A Sliding Scale Analysis. *The Journal of Law, Medicine & Ethics*. Winter 2004; 749-757

Kuczewski MG. Reconceiving the Family: The Process of Consent in Medical Decision-making. *Hastings Center Report*. Mar/Apr 1996; 30-37

Markowitz AJ, McPhee SJ. Caring for the Child With Cancer at the Close of Life. *JAMA.* March 2005; 293(11): 1382

McDonagh, J. (et al). Family Satisfaction with family conferences about end-of-life care in the intensive care unit: increased proportion of family speech is associated with increased satisfaction. *Critical Care Medicine. 2004;* Vol. 32, No. 7 pp. 1484-1488

Meert KL, Thurston CS, Briller SH. The Spiritual Needs of Parents at the Time of Their Child's Death in the Pediatric Intensive Care Unit and During Bereavement: A Qualitative Study. *Pediatr Crit Care Med.* 2005; 6(4): 420-427

Meert, KL, Thurston, CS. What Do Parents need at the Time of Their Child's Death in the PICU? *Crit Care Med 32(12): Suppl A89* (abstract to Poster Presentation: Ethics/End-of-Life/Compassionate Care Pediatrics).

Meert, KL; Thurston, CS; Thomas, R. Parental coping and bereavement outcome after death of a child in the pediatric intensive care unit. *Pediatr Crit Care Med*. 2001; 2(4):324-28

Meert, KL; Thurston, CS; Sarnaik, AP. End-of-life decision-making and satisfaction with care: Parental perspectives. *Pediatr Crit Care Med.* 2000;1(2): 179-85

Month S. Preventing Children From Donating Not in Their Interests. *BMJ*. 1995; 312:240-3

Meyer, EC; Burns, JP; Griffith, JL; Truog, RD. Parental perspectives on end-of-life care in the pediatric intensive care unit. *Crit Med Care*. 2002;30(1):226-31

Nelson JL. Taking Families Seriously. *Hastings Center Report*. July-August 1992; 6-12

Nelson JL. Physicians and Family Interests. *Crit Care Med*. July 2003; 31(7): 2072-73

Nelson HL, Nelson JL. *The Patient in the Family: An Ethics of Medicine in the Family*. Routledge 1995; 50.3:426p 74-81,200-203,216-217,234-235, 240-241

Perkins HS, Bauer RL, Hazuda HP, Schoolfield JD. Impact of Legal Liability, Family Wishes and Other "External Factors" on Physicians' Life-Support Decisions. *The American Journal of Medicine.* August 1990; 89:185-194

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. *Deciding to Forego Life-Sustaining Treatment.* March 1983; 134-136, 181-186, 211-223.

Puri VK, Weber LJ. Limiting the Role of the Family in Discontinuing of Life Sustaining Treatment. *The Journal of Medical Humanities.* 1990; 11(2): 91-99

Rabow, MW; Hauser, JM; Adams, J. Supporting Family Caregivers at the End of Life: They Don't Know What They Don't Know. *American Medical Association.* 2004;291(4):483-91

Rawls J. *A Theory of Justice*. Harvard University Press. 1999

Report of the Task Force on the Family. Family Pediatrics. *Pediatrics*. June 2003; 111(6): 1541-71

Rodney P. End of Life Decision-Making: The Cultures of Health Care Institutions as Problematic. February 1997; 186

Savulescu J. Substantial Harm but not Substantial Benefit. *BMJ*. 1996; 312:240-3

Seltzer, DL; Arnold, RM; Siminoff, LA. Are non-heart-beating cadaver donors acceptable to the public? *Journal of Clinical Ethics*. 2000; 11(4):347-57

Sharma, M; Meert, KL; Sarnail, AP. What Influences Parents' Decisions to Limit or Withdraw Life Support? *Crit Care Med. 32(12): Suppl A89* (abstract to Poster Presentation: Ethics/End-of-Life/Compassionate Care Pediatrics).

Shewmon, AD. The Dead Donor Rule: Lessons from Linguistics. *Kennedy Institute of Ethics Journal.* 2004; 14(3): 277-300

Siminoff, LA. Withdrawal of Treatment and Organ Donation. *Critical Care Nursing Clinics of North America. 1997; 9(1):85-95*

Siminoff LA, Chillag K. The Fallacy of the Gift of Life. *Hastings Center Report.* December 1999; 34-41

Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors Influencing Families' Consent for Donation of Solid Organs for Transplantation. *American Medical Association.* 2001; 286(1): 71-77

Siminoff LA, Burant C, Younger SJ. Death and Organ Procurement: Public Beliefs and Attitudes. *Social Science & Medicine*. 2004; (59):2325-2334

Thomasma DC, Pellegrino ED. The Role of the Family and Physicians in Decisions for Incompetent Patients. 283-292

Thompson, TL; Robinson, JD; Kenny, RW. Family conversations about organ donation. *Progress in Transplantation*. 2004;14(1):49-55

Truog RD. "Doctor, If This Were Your Child What Would You Do?" *Pediatrics*. August 1998; Commentaries 153-54

Ubel PA, Arnold RM**.** The Unbearable Rightness of Bedside Rationing: Physician Duties in a Climate of Cost Containment. *Arch Intern Med*. September 1995; 155(17): 1837-1842

Zucker A. Baby Marrow: Ethicists and Privacy. *Journal of Medical Ethics*. 1992; 18:125-127,141

APPENDIX I

TASK FORCE MEMBERS: BIOGRAPHICAL SKETCHES

Jackie L. Berlandi, RN, MS, CNOR
Jackie is a Nurse Manager in the Operating Room at Children's Hospital, Boston. In this role she is responsible and accountable for all aspects of many specialty services and perioperative staff, including professional growth and practice. She has been a nurse at Children's Hospital for many years, all of them in the operating room and in the roles of staff nurse, assistant head nurse of Plastic Surgery and Nurse Educator. Jackie received her diploma in nursing from the New England Deaconess Hospital School of Nursing, her BSN from Northeastern University and her Master's of Science in Nursing Administration from Boston University. She is a Certified Nurse Operating Room (CNOR).

Jackie is an active member of the Association of Operating Room Nurses (AORN), who served on various committees and the Pediatric Specialty Assembly. Jackie was elected to the AORN Nominating Committee and served as its chairperson. She is currently on the AORN Foundation Board of Directors. She was a member of the AORN Special Committee on Ethics, serving as its chairperson. In AORN Mass Chapter I Jackie served on many committees and in elected positions. She received the Mass Chapter I Award for Excellence in Perioperative Nursing. Jackie is also a member of MARN and Sigma Theta Tau.

Jackie has published various articles, posters and presented lectures on ethics and/or the pediatric patient and co-authored a chapter on the perioperative care of the pediatric patient in surgery. In 2003 she was one of the recipients of the APEX Award for Excellence for a nine part series published in the AORN Journal, titled "Ethics in Perioperative Practice."

Meg Comeau, MHA
Meg is currently the director of the Catalyst Center at the Boston University School of Public Health, a federally-funded national center dedicated to researching health care financing policy for children with special health care needs. She is also the chair of the Administrative Steering Committee and a member of the Medical Home Workgroup of the Massachusetts Consortium for Children with Special Health Care Needs. Additionally, Meg serves as a faculty member in the Program to Enhance Relational and Communication Skills (PERCS) at Children's Hospital Boston.

Prior to joining the Boston University School of Public Health in the summer of 2005, Meg had been a member of the Children's Hospital Center for Families staff for seven years, where she was the coordinator of the Family Initiatives program. In that role, Meg was responsible for facilitating family input into hospital policy and programming design. Her major projects focused on issues related to pediatric palliative care, bereavement support and improving family/professional communication. She was also the parent co-chair of the Family Advisory Committee, chair of the Family Faculty program and a member of the Ethics Advisory Committee at Children's Hospital.

Meg holds a master's degree in Healthcare Administration from Simmons College. She has earned several honors, including the Linda Roemer Scholarship for Excellence in Community Service from Simmons, a Young Investigator Award from the World Federation of Pediatric Intensive Care and Critical Care Societies for her work with Elaine Meyer, RN, PhD on parental design preferences in the pediatric intensive care unit, the David S. Weiner Award for Outstanding Leadership in Child Health (2000) from Children's Hospital Boston and the Simmons Healthcare Administration Program's Outstanding Student Achievement Award. Meg is a member of the Upsilon Phi Delta Honor Society for healthcare management.

Meg's personal life compliments her professional work. She is the mother of a nineteen- year old with a complex genetic disorder. She lives in Burlington with her husband and daughter.

David L. Coulter, MD
David is Associate Professor of Neurology at Harvard Medical School and Associate in Neurology at Children's Hospital Boston. He is currently the President of the American Association on Mental Retardation and serves as the Co-Editor of the Journal of Religion, Disability and Health. At Children's Hospital Boston he is also on the faculty of the LEND Program (Leadership Education in Neurodevelopmental Disabilities) and is the assistant director of the training program in neurodevelopmental disabilities here.

Dr. Coulter's interest in ethics spans 20 years or more. He was a member of the Multi-Society Task Force on PVS in 1993, and was a Fellow in the Harvard Bioethics Program in 1995. He recently completed a chapter on ethics for the new edition of the standard textbook in child neurology, and he attends the Ethics Consortium, which is led by Dr. Robert Truog. Dr. Coulter is interested in research ethics as well and serves on the Children's Hospital IRB as well as on the IRB for Harvard Medical School.

Nancy Craig, RRT
Ms. Craig is a Registered Respiratory Therapist with 20 years of clinical experience; 18 years in neonatal and pediatric respiratory care. Areas of interest include the care of patients with congenital diaphragmatic hernia, inhaled Nitric Oxide, and extracorporeal membrane oxygenation (ECMO). She is the Respiratory Care Supervisor who oversees the daily departmental operation; manages Respiratory Therapists in 3 intensive care settings; and provides consultation to ICU teams in both ventilator care and extracorporeal life support. Nancy is currently representing the hospital on a number of hospital-wide committees including the Ethics Advisory Committee.

Martha A. Q. Curley, RN, PhD, FAAN
Martha is the Director of Nursing Research for the Critical Care and Cardiovascular program and holds a concurrent appointment with the Data-Coordinating and Audit Committee. Martha was the Clinical Nurse Specialist in the MSICU previously for 14years. Currently, she serves as the Principal Investigator of several NIH funded studies (prone positioning in pediatric acute lung injury; sedation management in mechanically ventilated patients).

Martha is a primary architect of the Synergy Model, which serves as the blueprint for the CCRN and CCNS certification exams (credentials held by over 50,000 U.S. critical care staff nurse and clinical nurse specialists). She has pioneered studies on the Nursing Mutual Participation Model of Care, which provided structure to the concept of family-centered care. Ms. Curley is a recipient of the American Journal of Nursing's Critical Care Book of the Year Award (1997 and 2002) for Critical Care Nursing of Infants and Children. She has also been invited by the World Federation of Pediatric Intensive and Critical Care Societies to Co-Chair of the Scientific Committee for the 4th World Congress in Pediatric Critical Care.

William Edward Harmon, MD

Born in Cleveland, Ohio, Dr. Harmon is Chief, at the Division of Nephrology, Children's Hospital Boston. He graduated Summa Cum Laude, College of Holy Cross, Worcester, MA. *A.B.*; Case Western Reserve University, Cleveland, OH, *M.D.* Dr. Harmon serves as President of the North American Pediatric Renal Transplant Cooperative Study. His academic appointments include: Instructor of Pediatrics, Harvard Medical School, Assistant Professor of Pediatrics, Harvard Medical School, Associate Professor of Pediatrics, Harvard Medical School and Adjunct Associate Professor of Pediatrics, New York Medical College. Professional appointments include: Physician, Project Hope; The American Children's Hospital, Krakow, Poland; University of Indonesia, Jakarta, Indonesia; Consultant, University Renal research Association, Ann Arbor, Michigan.

PRINCIPAL CLINICAL AND HOSPITAL SERVICE RESPONSIBILITIES: Director, Dialysis Unit, Children's Hospital Boston; Attending Physician, Renal Transplant and Renal Consulting Services; Children's Hospital Boston; Attending Physician, Medical Service, Children's Hospital Boston; Director, Renal Transplant Program, Children's Hospital Boston.

Dr. Harmon also serves on numerous committees such as, Chairman - Department of Medicine Finance Committee; Capital Budget Committee; Physicians Organization: Managed Care Committee; Network Steering Committee; Joint Contracting Organization; Council of Chiefs; United Network for Organ Sharing - Multiple Listing Committee.

Charlotte H. Harrison, JD, MPH, MTS

Charlotte Harrison is a Clinical Ethicist in the Office of Ethics at CHB. She received her AB, Phi Beta Kappa, from the College of William & Mary and her JD from Harvard Law School. She practiced intellectual property law at the law firms Foley Hoag & Eliot and Palmer & Dodge and at Massachusetts General Hospital, where she was an associate director of the Office of Technology Affairs and co-chair of the Government Affairs Committee of the national Association of University Technology Managers. She served on the Board of Directors of Volunteer Lawyers for the Arts in Boston and on the staff of the Massachusetts Governor's Commission on the Unmet Legal Needs of Children. In addition to her law degree, Charlotte holds Masters degrees in Public Health and Theological Studies from Harvard University and is currently completing a Ph.D. at Harvard focusing on health care ethics. She has been a Fellow at Harvard Medical School (medical ethics) and at the Salzburg Seminar (international biotechnology policy). Prior to joining the staff at CHB she served as a community member of the CHB Ethics Advisory Committee and the DFCI Institutional Review Board.

Roberta Hoffman, LICSW
MSW, Boston University School of Social Work 1986. Social worker III, with 18 years experience at Children's Hospital Boston, providing psychosocial and child protection assessment, advocacy, emotional support, resource allocation, psycho-education and counseling related to coping with acute, chronic life-threatening illness and end of life care.

Roberta has been the clinical supervisor to MSW trainees and staff social workers since 1991. Senior leadership role in social work department medical-surgical unit; Co-chair: social work department Professional Education Committee, a member of the planning committee for Keeping Connections, Schwartz Rounds Planning Committee, a member of the DCD Task Force, Clinical Practice Committee for Renal Program, Advisory Committee and participant in Children's Hospital Experience Journal Project.

Patricia L. Kraft, JD
Associate consultant at Bain & Company from 1987 to 90; litigation associate at Goodwin Procter from 1993 to 95; deputy legal counsel, Office of Governor Weld from 1995 to 1996. J.D. from Harvard Law School in 1993. Currently active in several organizations including the Children's Hospital Patient Care Assessment Committee, Combined Jewish Philanthropies, the Boys & Girls Club of Boston, the Brookline Public Library, The Park School, The Media & Technology Charter High School and Gateway Arts. Lives in Brookline with husband and three young children.

Peter C. Laussen, MBBS
Peter Laussen, a native of Melbourne, Australia, graduated from Melbourne University Medical School in 1981 and completed fellowships in anesthesia and pediatric critical care medicine at the Austin Hospital and Royal Children's Hospital, Melbourne. He joined the Cardiac Anesthesia faculty at Children's Hospital Boston in 1992 and the Division of Cardiac Intensive Care in 1993. For the next 9 years, he divided his clinical time equally between attending in the Cardiac Intensive Care Unit and the cardiac operating rooms, and in April 2002 was appointed the Director of the CICU and Chief of the Division of Cardiac Intensive Care in the Department of Cardiology. In 2002, he became the first incumbent of the Dolly D Hansen Chair of Pediatric Anesthesia at Children's Hospital, and is an associate professor at Harvard Medical School where he serves on one of the medical school admission committees. In addition to over 90 co-authored original papers, chapters, editorials and commentaries on pediatric anesthesia and cardiac critical care, Dr Laussen's research efforts have included monitoring neurological function during and after cardiac surgery, monitoring the depth of anesthesia, evaluation of the stress response to surgery and evaluation of clotting function in children with certain forms of cardiac disease.

Craig Lillehei, MD
Dr. Lillehei received his degree from Cornell University and attended Harvard University Medical School. He is the surgical director of the kidney & lung transplant programs and a trustee for the New England Organ Bank. Dr. Lillehei has been involved with pediatric solid organ transplants for over 20 years and serves as a chairman on the Solid Organ Transplant Committee. He is Licensed/Certified on: National Board of Medical Examiners, Massachusetts License Registration, American Board of Surgery, American Board of Surgery - special

qualifications in pediatric surgery and American Board of Surgery Critical Care. He is a member of Massachusetts Medical Society, American Medical Association, New England Pediatric Surgical Association, American College of Surgeons, New England Surgical Society and American Academy of Pediatrics, surgical section.

Anne Jenks Micheli, RN, MS
Director of Perioperative Programs at CHB.

Adrienne Randolph, MD, MSc
Adrienne has been an attending physician in the MSICU at Children's Hospital Boston for almost 8 years. She is currently the Director of Patient Safety and QI for the MSICU and is a Senior Associate in Critical Care in the Department of Anesthesia. She is also an Associate Professor of Anesthesia at Harvard Medical School. Since 1999, she has been the Chair of the Pediatric Acute Lung Injury and Sepsis Investigator's (PALISI) Network, a consortium of over 50 North American PICUs who have joined together to perform multicenter studies. She has completed three studies across the PALISI Network including a 10-center randomized trial comparing three methods of weaning children from mechanical ventilator support, a 30-center observational study of transfusion practices and blood loss determinants, and a 9-center study to determine which children would be eligible for studies of interventions for acute respiratory failure. She has also performed two surveys studies in the PICU and the titles of the published reports were: "Factors explaining variability among caregivers in the intent to restrict life-support interventions in a pediatric intensive care unit" and "Variability in physician opinion on limiting pediatric life support". The first study was a single center study and the second was performed across 29 PICUs. Her current NIH research funding is in the study of the genetic epidemiology of RSV bronchiolitis and subsequent asthma. She prospectively follows over 420 children previously hospitalized at Children's Hospital Boston for RSV bronchiolitis to determine their long-term respiratory outcomes.

Rev. Mary Robinson, MA, M.Div.
Mary is the Director of Chaplaincy for CBH. She is board certified as a chaplain and is ordained as a minister in the United Church of Christ (the largest Protestant denomination in the Commonwealth of Massachusetts.) She coordinates the multi-faith Chaplaincy at Children's, which last year made 27,700 bedside visits. She is a graduate of Vassar College, the New School of Social Research (MA), and Drew Theological School (M.Div.) .She completed two years of Chaplaincy residency at Columbia Presbyterian Medical Center in New York City, where she was chief resident.

Mary attended the Kennedy Institute of Ethics Intensive Bioethics Course in 1993, and was a 2000 Fellow in Medical Ethics at Harvard Medical School. Over the years, she has served two terms on Children's EAC, two terms on the EAC at Children's Extended Care, as well as a one term each on the IRB's of Joslin and Judge Baker.

Mary was a member of the first CHB Task Force on the Refusal of Blood Products.

Patrick L. Taylor, JD
Patrick is Associate General Counsel at CHB. He graduated from the University of Wisconsin-Madison with a BA in Zoology and Philosophy, receiving Phi Beta Kappa and highest honors. He received his JD from Columbia University Law School in 1986, a Harlan Fiske Stone Scholar

each year based on academic performance, and having been awarded a teaching fellowship at Columbia in civil procedure.

After working for a federal appellate judge, he worked at the Wall Street firm of Cravath, Swaine and Moore, and later for New York City itself as an appellate attorney involved in issues involving health care, children, homelessness, education and poverty. For the latter work, including a record number of successful cases in New York's highest court, he won the Award for Outstanding Achievement of the Association of the Bar of the City of New York, and also the Corporation Counsel's award for outstanding promise in public service law. From 1991 through the end of 1994, he served as Assistant Counsel for Health and Human Services for New York Governor Mario M. Cuomo where he negotiated more than 30 pieces of major legislation, including the final comprehensive NYPHRM (including provisions to expand funding for physician training), creation and expansion of health coverage for children, health care and educational services for troubled and impoverished youth, foster care reform, almost a billion dollars in funding for distressed hospitals, affordable housing in poor urban areas, and the landmark Community Mental Health Reinvestment Act, which devoted funds from closing state hospitals to community support for mentally ill adults and children with severe emotional disturbances. He was also involved in the Governor's public writings on constitutional rights, education and health. Thereafter, he assisted the Speaker of the New York Assembly as Chief of Staff of the Education Committee and Senior Counsel to the Majority, leading staff negotiations for complete reorganization of the New York City schools, increasing school funding and accountability mechanisms, creation of accountable pre-kindergarten programs, and countless programs for disabled children requiring a combination of educational, mental health and social services. Later, for four and a half years, he served as Senior Vice President and General Counsel of Albany Medical Center in New York.

Professional associations include leadership positions with the Health Section of the New York State Bar Association, including as Chair of the In-house Counsel Committee and member of the Executive Committee. He has also taught health care legal and ethical issues as an adjunct professor at the Albany Medical College and the Albany Law School; was an associate of the Albany Medical College Center for Medical Ethics, Education and Research; and has served as a member of two institutional review boards, the IRB of the Albany Medical College and the IRB of Children's Hospital Boston.

Writings focus on conflicts among legal paradigms governing related areas, or integrating interdisciplinary approaches to a legal problem. Recent writings address conflicts of interest in biomedical research, and contrasting legal and ethical oversight of stem cell research.

Robert D. Truog, MD

Dr. Truog is Professor of Medical Ethics and Anesthesiology (Pediatrics) at Harvard Medical School and a Senior Associate in Critical Care Medicine at Children's Hospital Boston. Dr. Truog received his medical degree from the University of California, Los Angeles and is board certified in the practices of pediatrics, anesthesiology, and pediatric critical care medicine. He also holds a Master's Degree in Philosophy from Brown University. Dr. Truog's major administrative roles include Director of Clinical Ethics in the Division of Medical Ethics and the Department of Social Medicine at Harvard Medical School, Associate Director of the Office of

Ethics at Children's Hospital, Boston, Chair of the Harvard Human Subjects Research Committee at Harvard University, and membership on the Harvard University Faculty Committee of the Edmond J. Safra Foundation Center for Ethics.

His academic work has primarily centered on the ethical issues that arise in anesthesia and critical care, and he recently authored national guidelines for providing end-of-life care in the Intensive Care Unit. He lectures widely nationally and internationally. His writings on the subject of brain death have been translated into several languages, and in 1997 he provided expert testimony on this subject to the German Parliament. Dr. Truog is an active member of numerous committees and advisory boards, and has received many awards over the years, including The Christopher Grenvik Memorial Award from the Society of Critical Care Medicine for his contributions and leadership in the area of ethics. In 2000, Dr. Truog also received an honorary Masters of Arts from Harvard University in Cambridge.

Tamara Vesel, MD

Dr. Tamara Vesel is a pediatric palliative care physician at the Dana Farber Cancer Institute and Children's Hospital Boston and an Instructor in Medicine at Harvard Medical School. Dr. Vesel completed her undergraduate and medical degrees in Kosice, Slovakia. She finished her pediatric residency training in Slovakia as well as at Tufts New England Medical Center. Dr. Vesel proceeded to do her pediatric critical care fellowship at Yale New Haven Hospital. Meanwhile, she took graduate classes in philosophy and medical ethics at Brown University. Dr. Vesel worked as the medical director of the Pediatric Intensive Care Unit at Tufts New England Medical Center, where she received a "Teacher of the Year" award and a "Compassionate Physician" award. She continues to enrich her education with the exploration of mind and body medicine.

As a Rabkin Fellow at the Shapiro Institute, Dr. Vesel worked on developing several educational projects. One included development of a curriculum for a pediatric palliative care fellowship program, for which she recently became the director. She was also named as co-director of the Harvard Medical School course "Living with Life Threatening Illness" with Dr. Susan Block. Dr. Vesel is a faculty member of the HMS Center for Palliative Care: Program in Palliative Care Education and Practice

David A. Waltz, MD

Born in Detroit and raised in Rochester, MN, Dr. Waltz received an undergraduate degree at Carleton College in 1981 and an M.D. degree from the University of Chicago Pritzker School of Medicine in 1985. He was a residency in pediatrics at the University of Rochester, Rochester, NY. He came to Children's Hospital Boston for a Pediatric Pulmonology Fellowship in 1988 and stayed on after the fellowship as a staff member in the Division of Respiratory Diseases. He has been involved in lung transplantation at Children's Hospital since his fellowship days and took over as Medical Director of the Lung Transplant Program in 1995. Dr. Waltz also serves as the Cystic Fibrosis Center Director and Director of Bronchoscopy Services. In addition to clinical and administrative duties, he has been involved in several clinical research trials, predominantly involving cystic fibrosis.