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Matthew J Weiss

Laura Hornby

Bram Rochweg

Michael van Manen

Sonny Dhanani

*See next page for additional authors*

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**Authors**

Matthew J Weiss, Laura Hornby, Bram Rochweg, Michael van Manen, Sonny Dhanani, V Ben Sivarajan, Amber Appleby, Mary Bennett, Daniel Buchman, Catherine Farrell, Aviva Goldberg, Rebecca Greenberg, Ram Singh, Thomas A Nakagawa, William Witteman, Jill Barter, Allon Beck, Kevin Coughlin, Alf Conradi, Cynthia Cupido, Rosanne Dawson, Anne Dipchand, Darren Freed, Karen Hornby, Valerie Langlois, Cheryl Mack, Meagan Mahoney, Deepak Manhas, Christopher Tomlinson, Samara Zavalkoff, and Sam D Shemie

# Canadian Guidelines for Controlled Pediatric Donation After Circulatory Determination of Death—Summary Report\*

Matthew J. Weiss, MD, FRCPC<sup>1,2,3</sup>; Laura Hornby, MSc<sup>3</sup>; Bram Rochweg, MD, MSc, FRCPC<sup>4</sup>; Michael van Manen, MD, PhD, FRCPC<sup>5</sup>; Sonny Dhanani, MD, FRCPC<sup>6</sup>; V. Ben Sivarajan, MD, MSc, FRCPC<sup>7</sup>; Amber Appleby, RN, MM<sup>3</sup>; Mary Bennett, MD, FRCPC<sup>8</sup>; Daniel Buchman, MSW, PhD<sup>9</sup>; Catherine Farrell, MD, FRCPC<sup>10</sup>; Aviva Goldberg, MD, MA, FRCPC<sup>11</sup>; Rebecca Greenberg, RN, PhD<sup>12</sup>; Ram Singh, MD, FRCPC<sup>13</sup>; Thomas A. Nakagawa, MD, FAAP, FCCM<sup>14</sup>; William Witteman, MIS<sup>15</sup>; Jill Barter, MD, FRCPC<sup>16</sup>; Allon Beck, MD, FRCPC<sup>17</sup>; Kevin Coughlin, MD, MSHc, FRCPC<sup>18</sup>; Alf Conradi, MD, FRCPC<sup>19</sup>; Cynthia Cupido, MD, MSc, FRCPC<sup>20</sup>; Rosanne Dawson, LLB<sup>21</sup>; Anne Dipchand, MD, FRCPC<sup>22</sup>; Darren Freed, MD, PhD, FRCPC<sup>23</sup>; Karen Hornby, MSc<sup>3</sup>; Valerie Langlois, MD, FRCPC<sup>24</sup>; Cheryl Mack, MD, MA, FRCPC<sup>25</sup>; Meagan Mahoney, MD, FRCPC<sup>26</sup>; Deepak Manhas, MD, FRCPC<sup>27</sup>; Christopher Tomlinson, MD, FRCPC<sup>28</sup>; Samara Zavalkoff, MD, FRCPC<sup>29</sup>; Sam D. Shemie, MD, FRCPC<sup>3,30,31</sup>

**\*See also p. 1068.**

<sup>1</sup>Division of Pediatric Intensive Care, CHU de Quebec, Centre Mère-Enfant Soleil, Québec, QC, Canada.

<sup>2</sup>Department of Pediatrics, Université Laval Faculté de Médecine, Québec, QC, Canada.

<sup>3</sup>Canadian Blood Services Decreased Donation, Ottawa, ON, Canada.

<sup>4</sup>Department of Medicine & Department of Clinical Epidemiology & Biostatistics, McMaster University, Hamilton, ON, Canada.

<sup>5</sup>Division of Neonatal Intensive Care, University of Alberta & Stollery Children's Hospitals, Edmonton, AB, Canada.

<sup>6</sup>Division of Critical Care, Children's Hospital of Eastern Ontario, Ottawa, ON, Canada.

<sup>7</sup>Division of Paediatric Cardiac Intensive Care Unit, University of Alberta & Stollery Children's Hospitals, Edmonton, AB, Canada.

<sup>8</sup>Division of Critical Care, BC Children's Hospital, Vancouver, BC, Canada.

<sup>9</sup>Bioethics Program, University Health Network, Toronto, ON, Canada.

<sup>10</sup>Critical Care Medicine, Département de pédiatrie, CHU Sainte-Justine, Montréal, QC, Canada.

<sup>11</sup>Department of Pediatrics and Child Health, Faculty of Medicine, University of Manitoba, Winnipeg, MB, Canada.

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<sup>12</sup>Department of Bioethics, Hospital for Sick Children, Toronto, ON, Canada.

<sup>13</sup>Division of Paediatric Critical Care Medicine, Western University Children's Hospital, London, ON, Canada.

<sup>14</sup>Division of Critical Care, Johns Hopkins All Children's Hospital, St. Petersburg, FL.

<sup>15</sup>Information Specialist, Québec, QC, Canada.

<sup>16</sup>Division of Pediatric Intensive Care, Janeway Children's Health and Rehabilitation Centre, St. Johns, NL, Canada.

<sup>17</sup>Division of Pediatric Intensive Care, Victoria General Hospital, Victoria, BC, Canada.

<sup>18</sup>Division of Neonatal Intensive Care, Children's Hospital of the London Health Sciences Centre, London, ON, Canada.

<sup>19</sup>Division of Pediatric Intensive Care, University of Alberta & Stollery Children's Hospitals, Edmonton, AB, Canada.

<sup>20</sup>Division of Pediatric Critical Care, Hamilton Health Sciences, Hamilton, ON, Canada.

<sup>21</sup>Canadian Blood Services Legal Department, Ottawa, ON, Canada.

<sup>22</sup>Division of Pediatric Cardiology, Hospital for Sick Children, Toronto, ON, Canada.

<sup>23</sup>Division of Cardiac Surgery, University of Alberta Hospital, Edmonton, AB, Canada.

<sup>24</sup>Division of Nephrology, Hospital for Sick Children, Toronto, ON, Canada.

<sup>25</sup>Division of Pediatric Anesthesia, Stollery Children's Hospital, Edmonton, AB, Canada.

<sup>26</sup>Division of Pediatric Intensive Care, Alberta Children's Hospital, Calgary, AB, Canada.

<sup>27</sup>Division of Neonatal Intensive Care, BC Women's Hospital + Health Centre, Vancouver, BC, Canada.

<sup>28</sup>Division of Neonatology, Hospital for Sick Children, Toronto, ON, Canada.

<sup>29</sup>Division of Critical Care, Montreal Children's Hospital, McGill University Health Centre and Research Institute, Montréal, QC, Canada.

<sup>30</sup>Division of Critical Care, Montreal Children's Hospital, McGill University Health Centre and Research Institute, Montréal, QC, Canada.

<sup>31</sup>Department of Pediatrics, McGill University, Montréal, QC, Canada.

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Address requests for reprints to: Matthew J. Weiss, Département de pédiatrie Centre Mère-Enfant Soleil du CHU de Québec 2705 boul Laurier Local R1735 Québec, QC G1V 4G2; and Canadian Blood Services, Deceased Donation, 1800 Alta Vista Drive Ottawa, Ontario, K1G 4J5. E-mail: matthew-john.weiss@mail.chuquebec.ca

**Objectives:** Create trustworthy, rigorous, national clinical practice guidelines for the practice of pediatric donation after circulatory determination of death in Canada.

**Methods:** We followed a process of clinical practice guideline development based on World Health Organization and Canadian Medical Association methods. This included application of Grading of Recommendations Assessment, Development, and Evaluation methodology. Questions requiring recommendations were generated based on 1) 2006 Canadian donation after circulatory determination of death

guidelines (not pediatric specific), 2) a multidisciplinary symposium of national and international pediatric donation after circulatory determination of death leaders, and 3) a scoping review of the pediatric donation after circulatory determination of death literature. Input from these sources drove drafting of actionable questions and Good Practice Statements, as defined by the Grading of Recommendations Assessment, Development, and Evaluation group. We performed additional literature reviews for all actionable questions. Evidence was assessed for quality using Grading of Recommendations Assessment, Development, and Evaluation and then formulated into evidence profiles that informed recommendations through the evidence-to-decision framework. Recommendations were revised through consensus among members of seven topic-specific working groups and finalized during meetings of working group leads and the planning committee. External review was provided by pediatric, critical care, and critical care nursing professional societies and patient partners.

**Results:** We generated 63 Good Practice Statements and seven Grading of Recommendations Assessment, Development, and Evaluation recommendations covering 1) ethics, consent, and withdrawal of life-sustaining therapy, 2) eligibility, 3) withdrawal of life-sustaining therapy practices, 4) ante and postmortem interventions, 5) death determination, 6) neonatal pediatric donation after circulatory determination of death, 7) cardiac and innovative pediatric donation after circulatory determination of death, and 8) implementation. For brevity, 48 Good Practice Statement and truncated justification are included in this summary report. The remaining recommendations, detailed methodology, full Grading of Recommendations Assessment, Development, and Evaluation tables, and expanded justifications are available in the full text report.

**Conclusions:** This process showed that rigorous, transparent clinical practice guideline development is possible in the domain of pediatric deceased donation. Application of these recommendations will increase access to pediatric donation after circulatory determination of death across Canada and may serve as a model for future clinical practice guideline development in deceased donation. (*Pediatr Crit Care Med* 2017; 18:1035–1046)

**Key Words:** clinical practice guidelines; deceased organ donation; donation after circulatory determination of death; end-of-life care; ethics

Since the publication of the 2006 consensus Canadian recommendation (1), donation after circulatory determination of death (DCD) has become an increasingly frequent path to donation for adults (2). Implementation of pediatric DCD (pDCD) has lagged behind. According to 2014 data from Canadian Blood Services, DCD represented 21% of total national deceased donation, but pDCD made up only 8% of pediatric deceased donation. The purpose of this document is to provide rigorously developed, evidence-based guidelines that centers can use to develop pDCD in Canada.

One of the methods proposed by donation experts to improve pDCD practice is standardization and evidence-based recommendations (3). Current pDCD practice varies by jurisdiction and center (3, 4), likely as a result of the fact that no

national or international guidelines specifically address pDCD. As detailed below, we have employed a rigorous guideline development methodology, including an extensive literature review (5) and multidisciplinary consultation to create recommendations for all aspects of pDCD.

## METHODS

The guideline was developed by a multidisciplinary guideline development committee that included seven topic-specific working groups (WGs). Two patient-family partners, professional society partners, and an international expert provided external review. Funding was provided by Canadian Blood Services. No guideline development member disclosed any financial conflicts of interest with for-profit entities, though several were or are paid donor physicians associated with governmental not-for-profit organ donation organizations (ODOs), and others have active research and academic activities in organ donation.

The guideline development committee adhered to a rigorous development process based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methods and consistent with recommendations from several national and international bodies (6–9). The scope of the guideline included only controlled pDCD (e.g., after planned withdrawal of life-sustaining therapies [WLSTs]). Specifically, we defined uncontrolled pDCD, or donation after cardiac arrest outside of a WLST setting, to be outside the scope of these guidelines. The guideline development committee and WGs judged the quality of evidence and created evidence-to-decision tables before making either “strong” or “conditional” recommendations according to the GRADE approach (10). In cases where the guideline development committee felt that there was insufficient evidence or the balance of benefits and harms was likely neutral, no recommendation was made.

In addition to GRADEd recommendations, the guideline development committee formulated Good Practice Statements (GPSs) in cases where there was a large body of indirect evidence strongly supporting the net benefit of the recommendation or there was no reasonable comparator (11). Full consensus by all guideline development committee and WG members was achieved for all recommendations.

This report is a summary that does not include all the recommendations or the justifications. For all recommendations, justifications, complete GRADE tables for actionable recommendations, and a comprehensive description of the guideline development process, please refer to the full report available at <http://www.organsandtissues.ca/s/english-expert/leading-practices-public-awareness-and-education>. For a global review of the pDCD literature, please refer to the associated scoping review (5).

## RECOMMENDATIONS

### Ethics and WLST

#### *Good Practice Statements.*

- 1) pDCD is a medically and ethically viable pathway to provide access to deceased organ donation.
- 2) The option of deceased donation, including pDCD, should be routinely incorporated into end-of-life (EOL) care.
- 3) Healthcare systems should establish processes to ensure pDCD access.
- 4) Throughout the WLST and donation process, healthcare professionals must respect the dignity of the dying process.
- 5) The discussions and process of deceased donation should respect the beliefs and values of the surrogate decision makers and other loved ones involved.
- 6) In recognition of diversity of perspectives on pDCD, healthcare professionals should be allowed to conscientiously object to participation in pDCD.
  - a) In the case of healthcare professional objection, institutions should work to honor the surrogate decision makers’ wishes to donate.

*Justification.* The option to offer DCD as part of EOL care is universally supported by professional societies and ODOs that have examined the issue (1, 12–15), including two specific endorsements from the American Academy of Pediatrics (16, 17). Despite this broad consensus, some authors have expressed concerns around ethical aspects of pDCD (18, 19). Some individuals within the healthcare team may have differing views on the meaning and permissibility of deceased organ and tissue donation (OTD) based on societal, cultural, religious, and other personal beliefs (20). These concerns justify the above recommendation to allow conscientious objection by healthcare professionals to not participate in pDCD, consistent with other policy and position statements (12, 17, 21). However, considering the important role donation can play in the lives of donor families, these objections should not prohibit substitute decision makers and families from participating in pDCD if they so desire, which is why we emphasize that institutions should work to accommodate these requests using the principles of effective referral.

### Decision-Making Process for WLST

#### *Good Practice Statements.*

- 7) The decision to pursue WLST must not be influenced by donation potential and should proceed according to accepted medical practices.
- 8) The ODO, organ recovery, and transplant team must not be involved in the decision to pursue WLST or have direct contact with surrogate decision makers before WLST decisions are finalized.
  - a) Treating teams may contact ODOs to assess eligibility prior to the decision to pursue WLST, as long as there is no direct contact between the ODO and surrogate decision makers.
- 9) The decision to pursue WLST should be made before any discussion of OTD that is initiated by healthcare professionals.
  - b) If surrogate decision makers initiate organ donation discussions prior to the decision to pursue WLST, information may be provided, but consent discussions should be deferred until WLST decisions have been finalized.



- 10) Safeguards should be in place to ensure that mitigation of conflict of interest for the case where a patient who is a potential donor and a patient who is a potential recipient are being cared for in the same care unit.

*Justification.* In order to avoid real or perceived conflicts of interest, decisions pertaining to OTD must be kept as separate as possible from decisions regarding WLST. As is universally supported in the literature, the above recommendations support that WLST decision-making follow established, best practices regardless of pDCD potential (12–14, 16, 17, 22–26).

One area we believe merits particular attention is when a patient who is a potential donor and a patient who is a potential recipient are simultaneously cared for in the same unit. This possibility is more likely in pediatric than adult practice given the smaller number of recovery and transplant hospitals. We acknowledge this as a potential conflict and encourage systems to ensure ethical safeguards if the substitute decision maker is motivated to pursue donation in this setting. Measures to mitigate this potential conflict will depend on local context but could include ethics consultation or a second opinion from an uninvolved clinician.

## Eligibility

### *Good Practice Statements.*

- 11) Individual transplant programs, in collaboration with pediatric and neonatal healthcare professionals and ODOs, should determine criteria for donor eligibility, limits of warm, and cold ischemic time. Special consideration should be given for neonatal patients who are potential donors.
- 12) Coroners must be notified prior to donation proceedings according to provincial laws. If coroner evaluation and approval to pursue pDCD is required, this should be done prior to consent discussions with the surrogate decision makers.

*Justification.* We chose to limit our recommendations related to pDCD eligibility. Further national recommendations will require input from multidisciplinary groups, including transplant surgeons and physicians caring for recipients of pDCD organs, in order to form organ-specific recommendations. Current recommendations from groups such as the Canadian Society of Transplantation should inform these discussions, including those on high-risk donors (27). These criteria will be subject to change based on center experience, further research, and recommendations from organ-specific transplantation groups.

## Consent for pDCD

### *Good Practice Statements.*

- 13) Consent discussions for pDCD can include members of the care team, representatives of the ODO, or healthcare professionals from both groups.
- a) As stated in GPS 9 above, all discussions of organ donation initiated by healthcare providers must be deferred until after WLST decisions are finalized.

- 14) The person or team discussing consent should have extensive knowledge of the local process and should clearly identify their institutional affiliations.
- 15) Consent conversations with surrogate decision makers should include the opportunity to discuss beliefs and values around all aspects of pDCD, including death and death determination.
- 16) At minimum, the following information should be provided to surrogate decision makers regarding the pDCD process:
- Logistics of the process, including that WLST may be delayed due to pDCD logistics, and where WLST will occur,
  - The procedures and methods of determining death, including that these practices conform to accepted medical and legal standards,
  - Which organs are potentially eligible for recovery,
  - That consenting for pDCD does not guarantee organ recovery or transplantation,
  - If organ recovery is not possible, tissue donation may remain an option,
  - How EOL care would proceed if they decline organ donation or if recovery does not occur after attempted donation,
  - That the treating team has no influence over allocation, which may include allocation to adult or pediatric recipients,
  - That surrogate decision makers will be supported if they consent to or decline pDCD, and
  - That consent can be withdrawn at any time, including after the determination of death.
- 17) Tests and interventions prior to death (antemortem interventions) to facilitate donation in pDCD require specific and informed consent from the surrogate decision makers for each intervention.
- Antemortem interventions should only be undertaken with disclosure and consideration of risks and benefits to the patient who is a potential donor.
  - Antemortem interventions should not be intended to hasten death.
  - Antemortem interventions should pose no more risk to the patient than routine intensive care practices.
- 18) Antemortem interventions should be recognized as providing nonmedical benefit to the patient who is a potential donor by allowing realization of interest and intent to donate despite the fact that these interventions provide no medical benefit to the patient who is a potential donor. This justifies surrogate decision maker's authority to consent to interventions that pose no increased risk beyond routine intensive care practices despite no medical benefit to the patient who is a potential donor.

*Justification.* How best to engage in consent discussions was carefully considered for these recommendations. There is significant practice variability concerning which healthcare

professionals should be present during consent discussions. Regardless of whether an ODO representative is present during the consent request, we recommend that person have detailed knowledge of the local processes and procedures. Further discussion of training requirements for people requesting consent can be found under Actionable Recommendation 1. Furthermore, the stage in the EOL pathway at which ODOs are to be notified varies across jurisdictions, often related to requirements of mandatory reporting laws. The laws and local practices of reporting of a patient who is a potential donor should be carefully considered when establishing a pDCD protocol.

The understanding of consent for pDCD also requires an understanding of the distinction between consent for interventions before (ante) and after (post) mortem. It is outside the scope of these guidelines to extensively review the legal framework governing pDCD consent, but deceased donation in Canada is governed by provincial tissue gift legislation. Similar to the concept of “authorization” used more commonly in the United States, permission to proceed with donation under gift acts is different from, and legally less demanding than informed consent for treatment of a living patient (28). Consideration of benefit or harm posed to the patient, which forms the basis of informed consent to treatment, cannot be applied in the context of postmortem organ recovery any more than it can be applied to the processes of cremation or embalming (28).

pDCD, however, includes both authorization for postmortem organ recovery and consent for antemortem interventions that do require full informed consent. A question that is often raised in pDCD considerations is if substitute decision makers or families can give valid consent for a procedure that might cause harm or discomfort to the donor while providing medical benefit only to the organ recipient. Several authors (22, 29, 30), including the 2013 American shared position statement from the American Thoracic Society, the Society for Heart and Lung Transplantation, the Society of Critical Care Medicine, the Association of Organ Procurement Organizations, and the United Network of Organ Sharing (12), answer in the affirmative. Their rationale is that if the process presents potential risk of harm that is similar to routine intensive care practices, and the procedure is in line with parental values, an assumption of altruism is legitimate (22, 29). The benefit to the patient who is a potential donor is therefore allowing donation to proceed in order to fulfill family or surrogate desire to donate, and it is this benefit that justifies assumption of risk without direct medical benefit. This is consistent with the ethical reasoning supporting children’s participation in medical research where there is no hope for direct benefit to them. Furthermore, not allowing patients’ substitute decision makers or families to accept this level of risk in order to act altruistically in this circumstance would limit their autonomy (21). These arguments, however, are not universally accepted, and others claim that altruism on the part of an incompetent child cannot be assumed based on parental values (18). We conclude that divergent opinions regarding the ethical acceptability of such antemortem interventions would be a justifiable reason for healthcare professionals to excuse themselves from pDCD proceedings through conscientious objection.

It is impossible to specifically recommend how to weigh these risks and benefits in all the nuanced situations that will arise for individual patients (e.g., heparin administration to a patient with a remote history of an intracranial hemorrhage). It is the responsibility of the treating team, with appropriate ethical oversight, to ensure that protection of the interests of the patient who is a potential donor remains the primary concern throughout these situations.

Any test of organ eligibility or those specific for allocation (e.g., human leukocyte antigen matching) should be considered an antemortem test and should not be performed until consent for the pDCD process and required investigations has been obtained.

For further information regarding general best practices in organ donation consent, please consult the recent report from Canadian Blood Services (31).

**Actionable Recommendation.** “Should trained professionals versus professionals without specific training be used for approaching families for consent in the setting of pediatric donation after circulatory death?”

- 19) The panel did not make a recommendation regarding minimal required training of professionals approaching families for consent in the setting of pediatric donation after circulatory death.

*Justification.* Although several observational reports (32–43) suggest that trained requesting is effective at increasing consent rates, the only randomized controlled trial (44) showed no effect of involving trained ODO staff at the time of consent. None of these studies were exclusive to pediatrics or even DCD. Only one (33) of 13 references examined family satisfaction after the consent process as an outcome.

Considering the lack of conclusive evidence supporting benefit, and the substantial system investment that would be required to have trained requesters present at every consent conversation, we chose to not recommend for or against this intervention. For further information on effective requesting techniques in deceased donation, please refer to the recently published report from Canadian Blood Services (31).

## Procedures for WLST in the Context of pDCD

### Good Practice Statements.

- 20) WLST practice should be based on established ICU or hospital practices, policies, and guidelines.
- 21) The critical care team must be responsible for patient management between the decision to WLST and the determination of death.
- 22) The ODO, organ recovery, and transplant team must not be involved in any aspect of management of the dying process.
- 23) WLST may occur in the critical care unit, near the operating room, or in the operating room, as determined by surrogate decision makers’ preferences, institutional logistics, resources, and facilities.

- 24) Psychosocial, spiritual, and bereavement support should be provided to surrogate decision makers regardless of WLST location.
- 25) Wherever WLST occurs, surrogate decision makers and other loved ones should be given the option to be physically present with the patient who is a potential donor until the determination of death is complete.
- 26) The organ recovery team should not be physically present in the room until the determination of death has been completed and the surrogate decision makers are escorted from the bedside.
- 27) If a patient who is a potential donor is hospitalized where pDCD is not available, and the surrogate decision makers are motivated to donate, consideration should be given for patient transfer to a hospital that performs pDCD.

*Justification.* The fiduciary responsibilities of ICU clinicians are first and foremost to act in the best interest of his or her patient (12, 13, 16), and we therefore strongly support that in the event of a conflict in management goals between organ donation and optimal EOL care, care for the dying child should always take precedence. As universally supported in the published literature, WLST practices should be provided with minimal deviations from standard practice, including full support available for families (12–14, 16, 17, 21, 22, 25, 26, 45). Our group did not specifically deliberate on the issue of whether the practice of surgical preparation of the patient who is a potential donor (sterilization of the surgical field, draping, etc.) represented acceptable contact between the recovery team and the donor prior to death determination. In line with other recommendations, if this practice is required by the recovery team, it should be treated as an antemortem intervention requiring specific informed consent, and the recovery team should in no way otherwise influence EOL care. Also if practiced, this contact should not alter the recommendation that the recovery team not be physically present in the room at the time of death determination, and they should leave the operating room after surgical preparation is completed and before the parents enter.

## Time From WLST to Determination of Death

### Good Practice Statements.

- 28) A maximum time limit from the start of WLST to death, beyond which organs will not be recovered, should be established in collaboration with ODOs and local transplant teams.

*Justification.* The duration of acceptable warm ischemic time (WIT) should be locally informed and based on organ-specific concerns (13, 46, 47). Current practice in most pDCD centers recommends WIT of 30–90 minutes, depending on the organ to be recovered. Adult practices may vary from 1 to 4 hours depending on multiple factors, including limitations of access to operating rooms. Our guideline committee did not consist of transplant surgeons or posttransplantation physicians who could provide meaningful expertise into the effects

of various WIT thresholds on specific organs, and we therefore specifically chose not to make recommendations regarding the length of acceptable WIT.

**Actionable Recommendation.** “Should formal predictive tools versus no formal tool (clinical judgment) be used for predicting time of death within 30 or 60 minutes of WLST?”

- 29) The panel did not make a recommendation regarding use of tools to predict the time from WLST to death.

*Justification.* Though a prediction tool developed by Shore et al (48) has shown reasonable predictive value, it remains to be tested against clinical judgment or prospectively validated. Prediction tools cause no direct harm to a patient, may provide important information to the clinical team and surrogate decision makers, and are low cost. The risk, however, is if clinicians choose whether or not to pursue donation proceedings based solely on such a tool without understanding its strengths and limitations. Although future iterations may result in improved sensitivity and specificity, we currently do not recommend for or against the use of death prediction tools.

## Minimum Standards Required for Death Determination in pDCD

### Definition of Death Used for these Recommendations.

There is currently no Canadian federal, provincial, or territorial statute mandating how clinicians determine when a patient is dead. As there is also no widely accepted medical standard from Canadian professional societies, we have chosen, for the purposes of this guideline, to use the following definition taken from recently proposed guidelines at the World Health Organization:

The definition of death by circulatory determination: The permanent loss of capacity for consciousness and all brainstem functions, as a consequence of permanent cessation of circulation. Permanence is defined as loss of function that will not resume spontaneously and will not be restored through intervention (49).

This definition is consistent both with current accepted Canadian medical practice and the definitions used in the current clinical practice recommendations governing donation circulatory death in adults (1).

**Good Practice Statements.** The following includes a summary of current Canadian laws and practices governing deceased donation. These laws and recommendations should be understood to represent the minimum standards necessary to determine death. They do not preclude additional standards, as long as those standards are accepted prior to implementation by all stakeholders.

- 30) The dead donor rule must be respected within the context of pDCD.
- 31) Death must be determined by two physicians in accordance with accepted medical practice.
  - a) The two physicians must confirm their determinations concurrently at the end of a hands-off period of observation during circulatory arrest.



- 32) No physician who has active involvement in transplant procedures or allocation of donated organs shall take any part in donor death determination.
- 33) The minimum level of physician qualification required to determine death in pDCD is as follows:
- They possess the requisite skills and training. A particular level of specialty certification is not required, but skills and training should include ability to interpret monitoring used.
  - At least one of these physicians must be an attending physician staff in the ICU of the patient and possess full and current licensure for independent medical practice in the relevant Canadian jurisdiction.
  - The second physician could be on an educational register (e.g., residents, fellows), as long as they have the requisite skills and training.
- 34) The following criteria must be met before organ recovery:
- Circulatory arrest, defined as the absence of antero-gradе arterial circulation. See actionable recommendations 37 and 38 for the specifics of how to determine that absence.
  - A hands-off period of continuous observation of circulatory arrest during which no interventions are undertaken to facilitate donation. See recommendation below for duration of hands-off period.
  - At the end of this period, death is legally determined, and organ recovery may commence.
- 35) Recovery and transplantation of the heart in pDCD is consistent with the dead donor rule, as death is based on the permanent cessation of circulation.
- 36) The same criteria should apply to all potential pDCD donors including those undergoing withdrawal of mechanical circulatory support such as extracorporeal mechanical oxygenation (ECMO).

*Justification.* The definition of death used for these guidelines represents both current accepted Canadian practice and is consistent with evolving international consensus (49). The details of how cessation of circulation is determined and for how long are detailed below in actionable recommendations 37 and 38. pDCD, practiced according to these practices and definitions, respects the dead donor rule, defined as “vital organs should only be taken from dead patients and, correlatively, living patients must not be killed by organ retrieval” (50).

We have chosen to recommend that although the first physician determining death in pDCD must have a full, unrestricted license to practice, the second may be a trainee on an educational register. This recommendation considers that the death determination in pDCD requires skills or training that would be readily available to a resident or fellow undergoing training in a PICU or neonatal ICU (NICU). If the second physician is on an educational register, he or she should be reminded that they are not obligated to participate and that a decision to participate or no will not affect their evaluation. Also, the second physician need not be from a certain

specialty, as long as he or she possesses the capacity to determine death in this setting, specifically the ability to interpret an arterial catheter waveform tracing.

In GPS 32, active involvement in transplant procedures or allocation is defined as any involvement in postmortem surgical recovery procedures, discussions of which patient on the transplant wait list will receive the donated organs, or participation in any part of the transplantation procedure (including anesthesia of the recipient). Consultant physicians who might be involved in evaluating the patient for donor eligibility and might also care for a potential recipient (e.g., nephrologists) would be excluded from participating in the determination of death. As addressed in GPS 10, it is possible that intensive care physicians will be involved directly or indirectly with the care of both donor patients and those who receive transplanted organs from the same donor due to the limited number of PICUs in Canada. Ethical safeguards should be developed in these cases.

Regarding GPS 36, in the past, when DCD was more commonly referred to as “donation after cardiac death,” authors argued that determining death by irreversible loss of cardiac function precluded DCD cardiac transplantation (51, 52). However, our guidelines specifically define death as permanent loss of circulation in the donor. Whether the heart remains unresuscitated in the donor or is removed and resuscitated in another patient does not alter donor outcome: body and brain circulation remains permanently ceased in the dead donor (53). Thus, cardiac pDCD practiced according to these guidelines would respect the dead donor rule.

**Actionable Recommendation.** “Should arterial line versus palpable pulses and auscultation be used for confirmation of lack of antero-gradе circulation?”

- 37) We recommend that a well-functioning arterial catheter be used to confirm arrest of antero-gradе arterial circulation for the determination of death. (strong recommendation, low certainty in evidence)

*Justification.* Although not specific to a pDCD setting, data from studies designed to test clinicians ability to determine between low and nonpulsatile states suggest that even experienced PICU physicians commit errors (54–56). The panel strongly felt that palpation of pulse was an inadequate method to confirm lack of circulation. Arterial catheter monitoring is commonly used, easily interpreted, and objective. The recommendation to rely on arterial catheter monitoring assumes a functioning and verified arterial catheter. No other confirmation of loss of antero-gradе circulation (e.g., electrical asystole) is necessary when a well-functioning arterial catheter is in place. Although auscultation or palpation should not be used to confirm lack of circulation, they could be applied to verify that an observed flat waveform corresponds with the clinical state. We make no recommendation as to the required site of the arterial catheter.

Please see the full report for consideration of situations when an arterial catheter is not possible for technical reasons or due to surrogate decision maker refusal, including the use of other modalities such as echocardiography.

**Actionable Recommendation.** “Should 10 minutes hands-off time versus 5 minutes hands-off time be used for death determination in pDCD donors?”

38) We suggest 5 minutes of hands-off observation of arrest of circulation prior to determination of death. (conditional recommendation, very low certainty in evidence)

*Justification.* Currently, all Canadian adult and pediatric centers performing DCD use 5-minute hands-off period. During this 5-minute period, also sometimes referred to as a “no touch” period, no healthcare professional should have any physical contact with the patient, and the physicians determining death should be constantly observing the method used to confirm absent circulation. The period of time commences when no visible pulsatility is observable on a well-functioning arterial catheter waveform or after the last evidence of anterograde circulation (e.g., last opening of the aortic valve by echocardiography). If evidence of circulation is detected during the 5-minute hands-off period, the observation period should recommence until 5 full minutes of absent circulation are observed. This period is longer than any reported case of autoresuscitation after WLST (57, 58), and organs transplanted after this ischemic time have acceptable outcomes (59–61). However, based on the low quality of the reviewed autoresuscitation evidence and the fact that no reports compared organ outcomes using 5- versus 10-minute hands-off times, we chose to make a conditional recommendation.

## Ante and Postmortem Interventions

### Good Practice Statements.

#### Antemortem.

- 39) Any intervention or test that may pose discomfort to the patient who is a potential donor should be managed with analgesia and/or sedation as per standard ICU practices.
- 40) Consideration should be given to the timing of administration of any antemortem pharmacologic intervention in order to minimize any potential risks.

#### Postmortem.

- 41) Interventions that do or may reinstitute oxygenated brain blood flow after death must not be performed, including cyclic ventilation after reintubation for lung donation.
- 42) Only the organ recovery team may carry out postmortem surgical interventions.

*Justification.* The above recommendations emphasize that any antemortem intervention, including transfer of a patient who is a potential donor, carries the same requirements for informed consent, minimization of risk, and respect for the comfort of the patient as in routine care of ICU patients. Refer to the “Consent for Antemortem Interventions” section above for additional discussion.

Regarding postmortem interventions, our primary concern was the need to avoid interventions that might reestablish oxygenated brain blood flow. Absence of oxygenated brain blood flow is the key component of the determination of death, so

procedures that potentially reestablish that flow could violate the dead donor rule. Understanding that risk, we recommend that tracheal reintubation is permissible as long as cyclic ventilation is not provided. Through cardiopulmonary interactions, cyclic ventilation has the theoretical risk of restoring oxygenation and brain circulation, and its avoidance has been recommended by other groups (12, 14).

**Actionable Recommendation.** “Should Heparin versus no anticoagulation be used for pDCD as an ante mortem intervention?”

43) The panel did not make a recommendation regarding the universal administration of heparin in the setting of pDCD.

*Justification.* Given the lack of available evidence for benefit in pediatric or adult patients (62, 63) and concerns regarding any antemortem interventions that could cause harm to a patient who is a potential donor, we make no recommendation regarding routine antemortem heparin administration pDCD. If given, practices such as dose and timing of administration should be determined jointly by intensive care teams, ODOs, and transplant programs to ensure that harm to a patient who is a potential donor is minimized.

**Actionable Recommendation.** “Should regional oxygenated perfusion techniques versus no such techniques be used for improving organ outcome in controlled pDCD?”

44) We recommend that regional perfusion not be used in the setting of pDCD (strong recommendation, very low certainty in evidence).

*Justification.* Although not practiced in Canada, other jurisdictions have employed perfusion techniques (e.g., modified ECMO) that provide oxygenated blood flow to abdominal organs after death but prior to organ recovery, while excluding blood brain flow. Reports of this practice were considered indirect to our question, since they were almost exclusive to adult donors (64–74), and often involved antemortem interventions such as cannulation that would be in conflict with current Canadian pDCD practice.

Given the low quality of the evidence reporting benefit, risk of the significant consequence of reestablishing brain blood flow through inadequate aortic occlusion, and the cost/resources involved, we feel that regional perfusion techniques should not be used for pDCD (64, 73).

Although we do not recommend its use in standard practice, regional perfusion techniques could be considered as part of a research protocol with research ethics board approval. Oversight should include techniques to ensure the absence of brain blood flow during regional perfusion.

**Actionable Recommendation.** “Should bronchoscopy versus no bronchoscopy be used for ante mortem evaluation of lung function in potential pDCD donors?”

45) The panel did not make a recommendation for or against the routine use of antemortem bronchoscopy in the setting of pDCD.

*Justification.* Although bronchoscopy is frequently practiced in neurologic determination of death and DCD organ donation, its association with graft or recipient outcome in pDCD is not well described (75–77). We acknowledge that antemortem bronchoscopy prior to controlled pDCD is likely a low risk procedure, but there are no published reports evaluating adverse events rates in this setting. This balance of considerations led us to not recommend for or against antemortem bronchoscopy.

The possibility of postmortem bronchoscopy either in situ or ex vivo is unreported in the current literature but would likely be of similar benefit as a pretransplant bronchoscopic evaluation while eliminating risk conferred to the patient who is a potential donor.

### Cardiac pDCD

#### *Good Practice Statements.*

- 46) Considering the lack of published experience in cardiac pDCD:
- Cardiac transplant programs should establish criteria for acceptance of heart donation, ex vivo cardiac protocols, and heart allocation in pDCD,
  - Consideration should be given to initiate cardiac pDCD program as either research protocols with research ethics board oversight or through programs that oversee innovative therapies.

*Justification.* Although there is minimal published experience with cardiac pDCD (78), recent innovative reports of adult cardiac DCD using ex vivo heart preservation suggests that this option may evolve as a viable clinical pathway in the near future (79). We considered this lack of evidence when recommending that future Canadian cardiac pDCD should be undertaken under the supervision of a clinical trial or innovative therapy program.

### Neonatal DCD

#### *Good Practice Statements.*

- 47) Unless otherwise stated, the above GPSs and actionable recommendations that apply to infants and children should also apply to neonates, provided expertise in neonatal EOL care can be provided.
- 48) Diagnoses such as anencephaly or other similar severe, life-limiting neurologic disorders, for whom NDD is impossible, do not preclude consideration as potential candidates for pDCD.
- 49) Centers not providing pDCD should establish a clear process for transfer to hospitals with pDCD programs including consideration of transfer of the mother of the patient who is a potential donor, ongoing provision of EOL care, limitation of economic burden on surrogate decision makers, and repatriation of the body.

*Justification.* In general, we felt that there are more similarities than differences between neonatal and pediatric DCD practice. As with all potential DCD donors, optimal EOL care

should remain the fundamental concern in a neonatal pDCD process. The particular relational and ethical aspects of neonatal death require the expertise of a clinician trained to deal with these EOL issues (80, 81). Also, even less is known about the rate of the dying process after WLST in neonates and how that might affect completion of pDCD in this population, which should be discussed with surrogates during the consent process.

One of the potential differences between neonatal and other populations is the relatively large numbers of regional, nontertiary NICUs that do not offer pDCD (compared with relatively small number of PICUs) in which many potential neonatal pDCD donors may be initially hospitalized. If parents of children hospitalized in NICUs that do not offer pDCD wish to pursue pDCD, clear protocols for transfer would be necessary, including consideration that the mother might not yet be eligible for transfer or discharge (82).

We recommend that pDCD can be offered to patients born with anencephaly or other similar severe, life-limiting neurologic disorders. In 2016, the Canadian Paediatric Society reaffirmed its position statement (83) that recommends against allowing deceased organ donation in this population based on the impossibility to complete a NDD examination in the setting of a functional brain stem. This statement, however, was based solely on NDD. Since pDCD is unaffected by the fact that these patients do not fulfill NDD criteria, we recommend that pDCD can be offered to the substitute decision makers of patients born with this condition.

### pDCD Implementation and Oversight

#### *Good Practice Statements.*

- 50) pDCD programs should seek out formal institutional approval within the existing hospital reporting structure.
- 51) There should be an integrated, collaborative approach to pDCD implementation with all hospital stakeholders, family and/or public partners, regional ODOs, and transplant programs.
- 52) Local coroners should be contacted early in the process of developing local pDCD procedures.
- 53) Communication and education of staff should be considered a priority during the development and implementation of a pDCD protocol.
- 54) pDCD case management review, including regular debriefing and a periodic quality assurance process, should occur.
- 55) Support for healthcare professionals involved in pDCD should be provided.

*Justification.* The establishment of a pDCD program should involve multidisciplinary collaboration with oversight from appropriate local authorities. The need for communication and education of all involved stakeholders has also been broadly emphasized in recent publications and was a frequently expressed sentiment during our pDCD symposium (25, 81). Quality control for this low-frequency, high-impact event is critical for pDCD programs. This process should involve medical and ethical oversight, ideally with linkage to measures of



donor family experiences and transplant outcomes. Establishing robust ethical oversight also decreases the potential impact of institutional bias toward organ donation. Organ donation and transplantation activity are often a high-profile endeavor within a healthcare system, and the positive exposure associated with these programs may lead to a perception that donation activity takes precedence over ethical safeguards. The recognition and mitigation of this source of potential conflict interest is an important aspect of maintaining professional and public trust in the donation system.

Although we do not provide specific recommendation for documentation, inherent in the quality assurance component of recommendation 54 is the assumption that the process of pDCD be well documented. We encourage teams developing pDCD practices to visit the Canadian Blood Services website link listed below to see sample clinical and administrative checklists as well as documentation tools.

## CONCLUSION

These recommendations are the result of a 3-year development process and represent the first pediatric-specific, national guideline governing pDCD practice. The process was transparent and based on the best available evidence that was synthesized into recommendations using the most rigorous methods possible. Review of this literature highlighted several knowledge gaps that hopefully will be addressed by further research in the field (5). For further information regarding our methods and the justifications behind our recommendations, please visit <http://www.organsandtissues.ca/s/english-expert/leading-practices-public-awareness-and-education> for the full report in English and French, as well as tools to facilitate pDCD implementation. For questions regarding establishing a pDCD program, please contact Dr. Weiss or Canadian Blood Services.

Although no guideline can perfectly address all concerns held by all stakeholders, it is our sincere hope that application of these guidelines can increase the number of organs available to Canadians, while also offering the meaningful possibility of organ donation to families experiencing the loss of a child.

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