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REPORTS OF ORIGINAL INVESTIGATIONS

Improving quality of withdrawal of life-sustaining measures in organ donation: a framework and implementation toolkit

Amélioration de la qualité de l'interruption des traitements de maintien en vie lors du don d'organes : proposition d'un cadre et d'outils d'aide à la mise en œuvre

Andrew Healey, MD · Michael Hartwick, MD · James Downar, MD · Sean Keenan, MD · Jehan Lalani, MHA · Jim Mohr, MBA · Amber Appleby, RN MM · Jenna Spring, MD · Jesse W. Delaney, MD · Lindsay C. Wilson, MHA · Sam Shemie, MD · for Canadian Blood Services, the Canadian Critical Care Society, the Canadian Association of Critical Care Nurses, and the Canadian Society of Palliative Care Physicians

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Abstract

Background *Donation after circulatory determination of death (DCD) is responsible for the largest increase in deceased donation over the past decade. When the Canadian DCD guideline was published in 2006, it included recommendations to create standard policies and procedures for withdrawal of life-sustaining measures (WLSM) as well as quality assurance frameworks for this practice. In 2016, the Canadian Critical Care Society produced a guideline for WLSM that requires modifications to facilitate implementation when DCD is part of the end-of-life care plan.*

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A. Healey, MD (✉)
Division of Emergency Medicine, Department of Medicine, McMaster University, Hamilton, ON, Canada
e-mail: ahealeymd@gmail.com

Trillium Gift of Life Network, Toronto, ON, Canada

M. Hartwick, MD · J. Downar, MD
Department of Critical Care, The Ottawa Hospital, Ottawa, ON, Canada

Division of Palliative Care, Department of Medicine, University of Ottawa, Ottawa, ON, Canada

S. Keenan, MD
Division of Critical Care Medicine, University of British Columbia, Vancouver, BC, Canada

Donation Services, BC Transplant, Vancouver, BC, Canada

J. Lalani, MHA · J. Mohr, MBA · A. Appleby, RN MM · L. C. Wilson, MHA
Donation and Transplantation, Canadian Blood Services, Ottawa, ON, Canada

J. Spring, MD
Interdepartmental Division of Critical Care Medicine, Department of Medicine, University of Toronto, Toronto, ON, Canada

J. W. Delaney, MD
Departments of Critical Care and Medicine, Scarborough Health Network, Scarborough, ON, Canada

Division of Palliative Care, Department of Medicine, University of Toronto, Toronto, ON, Canada

S. Shemie, MD
Donation and Transplantation, Canadian Blood Services, Ottawa, ON, Canada

Division of Critical Care, Montréal Children's Hospital, Montréal, QC, Canada

McGill University Health Centre and Research Institute, Montréal, QC, Canada

Methods *A pan-Canadian multidisciplinary collaborative was convened to examine the existing guideline framework and to create tools to put the existing guideline into practice in centres that practice DCD.*
Results *A set of guiding principles for implementation of the guideline in DCD practice were produced using an iterative, consensus-based approach followed by development of four implementation tools and three quality assurance and audit tools.*
Conclusions *The tools developed will aid DCD centres in fulsomely adapting the Canadian Critical Care Society Withdrawal of Life-Sustaining Measures guideline.*

Résumé
Contexte *Au cours des dix dernières années, le don d'organe après un décès cardiocirculatoire (DDC) a été à l'origine de la plus importante augmentation de dons provenant d'individus décédés. Les lignes directrices canadiennes sur le DDC, publiées en 2006, recommandaient la création de politiques et de procédures standard pour l'interruption des traitements de maintien des fonctions vitales (TMFV) ainsi que celle de cadres d'assurance de la qualité pour cette pratique. En 2016, la Société canadienne de soins intensifs a publié des recommandations concernant les TMFV; ces recommandations nécessitent des modifications pour pouvoir être facilement mises en œuvre lorsque le DDC fait partie du plan de soins de fin de vie.*
Méthode *Un groupe collaboratif multidisciplinaire pancanadien s'est réuni afin d'examiner le cadre établi par les lignes directrices existantes et créer des outils pour mettre en œuvre ces recommandations dans les centres pratiquant le DDC.*
Résultats *En utilisant une approche itérative et consensuelle, un ensemble de principes directeurs a été créé pour mettre en œuvre des directives concernant la pratique du DDC : quatre outils d'implantation et trois outils d'assurance de la qualité et d'audit ont été mis au point.*
Conclusion *Les outils créés aideront les centres de DDC à adapter de manière plus complète les Lignes directrices pour l'interruption des traitements de maintien des fonctions vitales de la Société canadienne de soins intensifs.*

Keywords end-of-life care · withdrawal of life sustaining measures · organ donation · donation after circulatory death (DCD)

Donation after circulatory determination of death (DCD) accounts for the largest quantitative increase in deceased donation (48%) and transplantation over the past decade and constitutes 25% of deceased donation in Canada.[1] In the setting of an irrecoverable injury or illness, a consensual decision to withdraw life-sustaining measures (WLSM) is made and death is determined after permanent cessation of circulation.[2] Clinical practices supporting DCD have become embedded in the critical care culture across Canada. Transplantation following DCD is an effective life-saving treatment. The integrity of the donation-transplant system is predicated on public and professional trust. Any compromise of this trust can adversely impact donation system performance resulting in innumerable lives lost on the transplant wait list.[3,4]

Withdrawal of life-sustaining measures is the most common event preceding death in critical care and there remains considerable variability in WLSM practices.[5–7] In an attempt to address this variability, the Canadian Critical Care Society (CCCS) published a guideline for the WLSM in 2016.[8] As with many guidelines, without appropriate knowledge translation tools, implementation of the guideline will be slow with variable uptake.

Canadian healthcare professionals (HCP) may face challenges in both practice and perception when providing WLSM in the context of DCD.[6,9] While only a small portion of patients undergoing WLSM may be eligible donors,[10] there is the potential for increased complexity when WLSM occurs in situations where organ donation is planned. While the WLSM processes may remain similar to those in non-donor patients, WLSM in the context of DCD may introduce different personnel, a different clinical setting (near the operating room), and different time constraints. Expectations of both patient/families and clinicians may also differ and specific ethical safeguards must be observed. Approximately one-third of potential DCD donors do not die before their organs have suffered too much ischemia to make donation possible.[11] Families have described "hoping for death in time" as very difficult, and the death that occurs beyond a time where organs can be safely transplanted as a "second loss."[9,12] During the dying process after WLSM, ethical and legal tensions and questions arise despite the agreement that fulfilling the wish of the dying patient to be a donor and providing a comfortable death are goals of the process. For example, these goals must be achieved without expediting death for donation as this would be illegal in 2020, outside of the context of medical assistance in dying.

Guiding principles and tools are required to assist HCPs in acting within these frameworks. The full implementation of the CCCS WLSM guideline will protect the potential donor, the HCPs, and by protecting the system, the recipients of life-saving transplants.

While the CCCS WLSM guideline provides us with a framework for WLSM, it does not account for the modifications necessary when donation is part of the end-of-life care plan. When donation is to occur, time is required to coordinate the many tasks. It is clear that this makes the situation more complex and requires additional assistance beyond that offered by the CCCS WLSM guideline. In addition, the guideline does not provide tools for implementation or audit that would assist guideline implementation and quality assurance (QA) in the intensive care unit (ICU). Uncertain practice standards and misperceptions may challenge HCPs and families, and lead to misunderstandings or complaints which ultimately have the potential to erode trust in life-saving services such as critical care and organ donation.

The stewardship of public and professional trust in the donation system is shared by organ donation organizations, Canadian Blood Services, and critical care, with national physician representation by the CCCS. Canadian Blood Services and the CCCS partnered to produce a framework for knowledge translation of the CCCS WLSM guideline: a set of guiding principles, clinical tools to support implementation, a QA framework, and a WLSM policy template for Canadian hospitals that offer DCD. This framework is supported by a multidisciplinary development process and is endorsed by our national practice societies, including CCCS, the Canadian Association of Critical Care Nurses, and the Canadian Society of Palliative Care Physicians.

Objectives

There is a need for clear, pragmatic principles and tools to implement the CCCS WLSM guideline and to measure success in the setting of DCD, where the potential erosion of trust poses risks to the individual patient as well as to the donation system as a whole. The objectives are two-fold:

(1) Provide easily modifiable tools to (a) translate the current CCCS WLSM guideline into clinical practice in the context of donation, and (b) evaluate the implementation of the guideline; and
(2) Provide an actionable framework and evidence-derived tools to improve the quality of WLSM in DCD.

Methods

Canadian Blood Services and the CCCS brought together thirty-eight participants (see eAppendix 1, available as Electronic Supplementary Material [ESM]) with pan-Canadian perspectives including family partners and HCPs in critical care medicine, palliative care, organ and tissue donation, bioethics, nursing, respiratory therapy, social work, spiritual care, and death investigation (i.e., provincial coroner) for a two-day workshop aimed at translating the CCCS WLSM guideline into a framework for practice.

The scope of the workshop included all adult and pediatric ICU patients in whom the decision to withdraw life-sustaining measures has been reached between patient/family members/substitute decision makers (SDM) and the healthcare team and included clinical care processes from the first step of WLSM to death. While we focused on hospitals supporting DCD programs, it was recognized that the application of these QA tools could benefit all hospitals. We explicitly designated prognostication, decisions regarding WLSM, donor management, and medical assistance in dying as beyond the scope of this workshop.

Process

Participants were provided with a comprehensive background package including a literature review[7] with a supplementary update along with the CCCS WLSM guideline,[8] the Canadian DCD guideline,[2] and The Donation Physician Ethics Guide.[13]

An environmental survey of Canadian critical care units and organ donation organizations was also provided, including existing WLSM checklists, policies, order sets, education materials, flow sheets, and family information booklets.

Initially, workshop participants developed guiding principles for WLSM in the context of DCD through an iterative process. To inform the process, expert presentations focusing on the development and content of the CCCS WLSM guideline, implementation, death investigation, and QA were followed by presentations of unique experiences from family partners.

In advance of the meeting, draft QA tools were developed by the steering committee based on the 2016 CCCS WLSM guideline and common elements from the expansive environmental scan.

Workshop participants were provided with condensed summaries of the 2016 CCCS WLSM guideline[8] and the draft implementation tools. Working in small groups, participants were asked to identify strengths, gaps, areas of concern, and recommended revisions to the implementation tools, which were vetted by the plenary group. After determining alignment with the requirements in the guideline, and consensus at the meeting, recommended revisions were incorporated.

The guiding principles, key concepts, and recommended revisions were then brought back to the steering committee for consensus on the content of the QA toolkit. The revised toolkit was then returned to the participants for their endorsement. There was unanimous agreement on the final tools and recommendations presented here.

Results

A framework was endorsed by national critical care societies, including a set of guiding principles, tools to support implementation and QA, and a policy template for WLSM focused on Canadian hospitals which offer organ and tissue donation. Consensus was achieved on three core principles as proposed by the steering committee and refined by conference participants:

(1) It is imperative that end-of-life care in the critically ill be of the highest quality, in all circumstances, including that of organ and tissue donation.
(2) Implementation tools will support critical care programs in translating the CCCS WLSM guideline into clinical practice in hospitals that perform DCD.
(3) Withdrawal of life-sustaining measures QA processes should be in place at all hospitals offering organ and tissue donation.

Through vigorous table and plenary discussions, conference participants provided the following expert advice regarding the practical materials developed and refined during the conference. Given that the results are not formally graded, we have entitled them as expert guidance, in contrast to recommendations.

It is imperative that end-of-life care in critically ill patients be of the highest quality, in all circumstances, including that of organ and tissue donation

The principles of expert inter-professional critical care must foster a seamless transition into end-of-life care. These principles of person-centred care in the ICU must be maintained throughout conversations, assessments, and procedures involved in organ and tissue donation. These principles form the basis for an approach to expert palliative care in the ICU and the preservation of public trust in the donation system.

Patients experience this care and family members/SDMs live with a lasting impact of their experiences in WLSM and donation. While it is acknowledged that individual WLSM plans may be subject to variability in response to patient/family/SDM priorities, these principles of high-quality care must be unwaveringly maintained.

Implementation tools support critical care programs in translating the CCCS WLSM guideline into clinical practice

To effectively implement the CCCS WLSM guideline, templates for tools are required. The developed tools are attached as appendices and expert guidance on their utilization is described below.

We suggest:

(a) A local QA and/or quality improvement (QI) group should review the tools and WLSM process;
(b) The local QA/QI teams have patient and family representation; and
(c) The local QA/QI teams sequentially review the proposed tools for applicability to the local environment, make required modifications, and use established iterative QI methodology to implement the toolkits and measure success.

Standardized WLSM order set (eAppendix 2, available as ESM)

A sample order set template was developed. The order set exists as a clear plan for symptom management, developed and discussed in advance of apparent symptoms, so HCPs and families are clear on a plan. This may mitigate both a reluctance to treat symptoms to avoid the perception that too much medication has been given and the administration of excessive medications to treat symptoms that are not apparent.

We suggest:

(d) Sections of the order set address (i) ways in which the stage is set for WLSM; (ii) pharmaceutical management of distress (pain, dyspnea, anxiety, agitation); and (iii) the means and methods by which WLSM should happen; and
(e) As part of the checklist, the order set should be reviewed by the team providing care for the patient during the preparation that occurs prior to WLSM.

Withdrawal of life-sustaining measures checklist (eAppendix 3, available as ESM)

The WLSM process is complex and made even more complex by the introduction of the DCD consent and preparation processes. A checklist for the team to review prior to the process of WLSM was developed.

An additional section for DCD highlights those special considerations for DCD potential donors.

We suggest:

(f) The checklist be used at the bedside to ensure those actions and steps suggested by the guideline have been addressed systematically.

Withdrawal of life-sustaining measures documentation tool template (eAppendix 4, available as ESM)

A documentation tool that links symptoms, drug administration, and response to treatment was developed. The purpose was to provide appropriate documentation to ensure adherence to principles of WLSM (Table 1) and to protect against misinterpretation of intent when terminal sedation is administered.

Concern was ubiquitously expressed around the frequent missing link between symptoms and drug administration in documentation. As this is where most tension and confusion arise (i.e., around the purpose of the intended medication or dose), a clear need to improve documentation was identified, particularly when comfort is difficult to achieve. Workshop participants felt many other tools currently available in clinical practice were inadequate because of the dynamic nature of this particular situation and the need to be present with family members.

We suggest:

(g) Documentation of the actions and patient assessments around the time of WLSM should clearly and unequivocally link symptoms and drug administration;
(h) Regardless of format, documentation should be centred around ensuring adherence to the aforementioned WLSM principles (Table 1);
(i) All centres practicing DCD adopt a symptom-linked documentation tool allowing staff to rapidly document while preserving patient and family interactions; and
(j) Each site should adopt the documentation tool to fit with local practice (e.g., objective scales for symptom assessment *vs* symptom list).

Withdrawal of life-sustaining measures family information (eAppendix 5, available as ESM)

Families and healthcare professionals reflected on the need for written documentation and tools to assist families in understanding the complexity of the actions that occur prior to, during, and after the WLSM. The information leaflet assists families in receiving information in multiple formats when information is most difficult to absorb.

We suggest:

(k) The family be provided information in written form about WLSM and donation; and
(l) The family information tool could be used as a stand-alone tool or incorporated into other resources available provincially or at the hospital level.

Withdrawal of life-sustaining measures QA processes should be in place at all hospitals offering organ and tissue donation

Quality management focuses on how services are delivered, how well a service is provided in relation to the expected service requirements and how these services are improved; specifically, the processes of accountability and process improvement that need to be in place to respond to quality incidents. The Canadian DCD guideline[2] and the CCCS WLSM guideline[8] both recommend QA processes be in place.

Withdrawal of life-sustaining measures system audit (eAppendix 6, available as ESM)

It is necessary to understand and measure whether the CCCS WLSM guideline has been implemented in various hospital systems. This is of interest to hospitals and organ donation organizations who support DCD processes.

This resource is a list of recommended requirements at a hospital level that would be put into place, in advance of WLSM, to support professionals and families in the process, as determined by the guideline. This tool could be used by the organ donation organizations to engage in communication with the hospital stakeholders around quality management in this regard.

We suggest:

(m) This document be utilized as the first audit prior to fulsome implementation as it allows the QA committee to objectively identify gaps in current structures and processes around WLSM and DCD; and
(n) Each hospital who performs DCD complete the audit to identify gaps and work collaboratively with organ donation organizations around quality management of the DCD process.

Withdrawal of life-sustaining measures case audit (eAppendix 7, available as ESM)

Organ donation committees, ICU councils, or intensivists may wish to audit a series of WLSM cases in a random or systematic sampling activity at the local units after the CCCS WLSM guideline has been implemented. This tool, used on a case-by-case basis, evaluates adherence to

Table 1 Guiding principles in defining high-quality end-of-life care

High-quality end-of-life care:
• maintains dignity, respect, and compassion
• explores the wishes and voices of the patient and family/SDM
• respects culture, spiritual values, and observances
• continues to support and partner with patients, families/SDM, and the healthcare team throughout the death experience
• is consistent with guidelines for WLSM
• focuses on alleviating pain, distress, and providing comfort
• adheres to the current existing medicolegal framework, which in 2020 includes respect for the dead donor rule and precludes intentional hastening of death (notwithstanding medical assistance in dying legislation)
• avoids unnecessary prolongation of the dying process
• preserves the opportunity to donate organs and tissues

SDM = substitute decision maker, WLSM = withdrawal of life-sustaining measures

components of the WLSM guideline recommendations. Cumulative analysis of a series of cases of WLSM may identify opportunities for process improvement with the system (hospital).

This activity is supported by continuing medical education credit and offers insight not obtainable from other activities.

We suggest:

- Physicians use this tool to examine their own practice to identify gaps compared with the current established guideline;
- This is not a mandatory component of implementation but is a valuable activity that should be left to the discretion of individual healthcare providers or hospitals.

Withdrawal of life-sustaining measures policy (eAppendix 8, available as ESM)

While individual needs for a policy framework will vary from hospital to hospital, it is often helpful to begin with common structure and tailor the specific policy to meet the needs and interests at the hospital. This policy framework provides minimum specifications to implement the guideline effectively.

We suggest:

(q) Intensivists and donation-focused physicians review the need for a policy framework; and

(r) The policy be utilized as a template but that it be individualized to the environment in which it will be implemented.

Discussion

Many high-quality guidelines have been produced for use in critical care settings for the prevention, diagnosis, and treatment of critically ill patients.[14,15] Nevertheless, we frequently fail to translate these guidelines into practice.[16,17] Several reviews have examined strategies to improve guideline adherence; however, not surprisingly, there is no panacea.[16,18,19] Interventions that include protocols with or without education seem to be associated most strongly with practice change.[20] Without an excellent quality guideline and a carefully planned, purposeful, knowledge translation strategy, practice will not change. It is clear that in the complex ecosystem of the ICU, no one intervention will work for every ICU or every patient.[20]

The Institute of Medicine provide a description of attributes of high-quality guidelines,[21] many of which are fulfilled by the CCCS guideline on WLSM.[8] Strategies for guideline implementation including algorithms, audit and feedback, education, and concise recommendations (order sets) are provided to aid in implementation of this guideline.

The CCCS guideline for WLSM provides expert guidance. The tools developed through this broad multidisciplinary approach provide the end-user with guidance for implementation and audit and feedback within the system. The specific circumstance of donation following death by circulatory criteria requires some modification of the guideline and the tools provide explicit guidance for how that can be managed transparently. The broad range of perspectives, including family partners and front-line HCPs, strengthens the output of this collaboration. Our family partners contributed fully to the workshop, often challenging assumptions held in the

room and providing reassurance that focusing on comfort was a priority.

Clearly the tools provided will not fit every institutional context. Nevertheless, recognizing the complex adaptive system approach to change, it will be necessary for hospitals to develop and refine the templates for their individual culture.[22,23] Despite this being a weakness of any knowledge translation strategy, the tools here are produced as open-source and can be modified freely to fit the context of use.

Throughout the workshop, participants identified key unanswered questions and research opportunities in relation to WLSM and deceased donation. Several studies have clearly shown the feasibility of high-quality research in this area.[6,24,25] A summary of the generated research agenda can be found in eAppendix 9, available as ESM.

Conclusion

To enhance adoption of the 2016 CCCS WLSM guideline, particularly in hospitals that provide DCD donation, and address challenges in providing WLSM in the context of organ and tissue donation, Canadian Blood Services and CCCS convened a meeting of national stakeholders. The clearest message from the workshop was the resolve that high-quality end-of-life care is an expectation in every critical care unit in Canada. It is essential that end-of-life care be of the highest quality in circumstances where organ and tissue donation is offered. The development of a nationally endorsed framework including principles, policy as well as implementation, and QA tools for WLSM is an essential starting point for Canadian hospitals who offer organ and tissue donation.

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