



Knowledge gaps in the definition and determination of death

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Current practices for determining death by neurologic criteria (DNC) and death by circulatory criteria (DCC) are mainly based on guidelines developed by a consensus process relying heavily on foundational historical practices. *Death by neurologic criteria* was rooted in the Harvard *ad hoc* criteria¹ with 50 years of progressive evolution to the World Brain Death Project,² but suffers from insufficient direct evidence, and therefore, perpetual debate and unresolved controversies.^{3,4} *Death by circulatory criteria* has been derived from consensus and expert “accepted

medical practices.”⁵ While death affects every one of us, the scientific research base for determining death remains in early development, and many questions surrounding the dying process and death in critical care remain unanswered.

In this *Reflections* article, we explore the knowledge gaps related to various aspects of the definition of death and the criteria for determination of death that were identified during the development of the new Canadian Death Determination Guidelines.⁶ These Guidelines include a brain-based definition of death and recommendations for death determination by circulatory and neurologic criteria. They were developed according to the principles delineated by the Appraisal of Guidelines, Research and Evaluation II instrument for guideline assessment,⁷ with broad stakeholder engagement that included patient family members and the public. The

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Grading of Recommendations, Assessment, Development, and Evaluation approach⁸ was used to link the quality of the evidence to the strength of the recommendations. During the development of these guidelines, working group members highlighted the deficiency in high-quality evidence to support the generated recommendations. This is reflected by the overall low level of certainty in evidence for many of these recommendations. While other conceptions of death are legitimate, we intend to explore the knowledge gaps surrounding the brain-based definition of death and create opportunities for researchers to make progress in understanding the physiologic and medical dimensions of the dying process and its repercussions on society, patients, and families. The knowledge gaps we identified as those that should be prioritized to be addressed are presented in Tables 1, 2, and 3.

Knowledge gaps

Death determination by neurologic criteria

Clinical assessment is the cornerstone of DNC. International guidelines are unequivocal about the various steps it should include.² Nevertheless, several recommendations lack sufficient evidence to make strong recommendations. For example, a prospective study

successively examining the clinical features of DNC in patients after cardiac arrest would be warranted. Future research should address the dose-dependent effects of various confounders in DNC.

A single DNC clinical assessment observed by two clinicians is recommended in adults. Nevertheless, patients with decompressive craniectomy were underrepresented in the evidence supporting a single clinical exam. This population merits further attention regarding the potential reversal of DNC clinical features and the mechanism and timing of potential reversibility.⁹ A full clinical assessment documenting brainstem areflexia is required, but investigations updating the hierarchical value of each specific brainstem reflex to confirm DNC in various populations are lacking.

We identified several knowledge gaps connected with apnea testing. No prospective studies have compared the universally accepted threshold of 60 mm Hg for arterial partial pressure of carbon dioxide (PaCO₂) with higher PaCO₂ levels, depending on age, altitude, and baseline level. A prospective study comparing the frequency of completed apnea tests using exogenous CO₂ vs conventional practice would provide higher-quality evidence. The concern regarding the potential harm of hypercarbia induced by apnea testing merits study. More practically, though common in practice, future studies should examine the influence of positive airway pressure

Table 1 Selection of knowledge gaps about determination of death by neurologic criteria

Medical and physiologic dimensions

- 1.1. What is the required time interval between injury or ROSC and DNC to ensure permanence of clinical findings?
- 1.2. What is the pattern of loss of brainstem reflexes? Is there a hierarchy among them in DNC?
- 1.3. How often does a second clinical exam differ from the first one in neonates and infants?
- 1.4. What is the time window for potential reversibility of clinical signs after decompressive craniectomy?
- 1.5. Does volumetric analysis by serial neuroimaging after decompressive craniectomy provide information that can impact the certainty of DNC?
- 1.6. What are the effects of drug confounders on DNC? What are their dose-dependent effects on DNC?
- 1.7. What are the sensitivity and specificity of quantitative pupillometry and traditional pupillary assessment?
- 1.8. What is the PaCO₂ threshold generating respiratory drive depending on age, altitude, and baseline level?
- 1.9. Does exogenous CO₂ administration during apnea testing increase the chance of completion?
- 1.10. Does the theoretical potential for hypercarbic cerebral vasodilatation related to the apnea test increase intracranial pressure?
- 1.11. What is the influence of applying positive pressure during apnea testing?
- 1.12. What are the characteristic differences between DNC patients with and without preserved hormonal function and temperature regulation?

Social and ethical dimensions

- 1.13. What are the family member perspectives of care in cases of DNC, their understanding of DNC, along with their bereavement needs and outcomes?
- 1.14. What are the impacts for relatives of witnessing the DNC assessment? Does it improve understanding and acceptance of DNC? Is it an additional source of psychological trauma?

DNC = determination of death by neurologic criteria; PaCO₂ = arterial partial pressure of carbon dioxide; ROSC = return of spontaneous circulation

Table 2 Selection of knowledge gaps about determination of death by circulatory criteria*Medical and physiologic dimensions*

- 2.1. What is the minimum pulse pressure and pulse frequency that generates cerebral blood flow, perfusion, and function?
- 2.2. What is the minimal pulse pressure that an invasive blood pressure monitoring equipment can discriminate?
- 2.3. Are there noninvasive monitoring devices with high sensitivity and specificity profiles for accurate pulselessness detection?
- 2.4. What are the characteristics of autoresuscitation and prediction of time to death in neonates, children, and patients undergoing MAID?

Social and ethical dimensions

- 2.5. What is the influence of palliative care and WLSM practices on time to death and families' experiences?
- 2.6. What are the families' experiences and perspectives about WLSM and DCC, along with bereavement needs and outcomes?

DCC = determination of death by circulatory criteria; MAID = medical aid in dying; WLSM = withdrawal of life-sustaining measures

Table 3 Selection of knowledge gaps about ancillary testing*Medical and physiologic dimensions*

- 3.1. What are the sensitivity and specificity of the ancillary tests in various populations (newborns, infants with open fontanelle, patients with decompressive craniotomy, patients with isolated infratentorial brainstem injury)?
- 3.2. What are the reliability and cost-effectiveness of ancillary tests for DNC?
- 3.3. What is the validity of brainstem auditory and somatosensory evoked potential?
- 3.4. What are the dose-dependent effects of drug confounders on electrophysiologic and brain blood flow ancillary tests?
- 3.5. Which ancillary tests can measure brain function and investigate the brain and the brainstem without being susceptible to confounders?

Social and ethical dimensions

- 3.6. What are the families' perspectives about ancillary testing?
- 3.7. How does an ancillary test influence the families' understanding and acceptance of the DNC?
- 3.8. Does an ancillary test increase acceptance of DNC for families who express misunderstanding of DNC or in situations of potential conflict?

DNC = determination of death by neurologic criteria

on DNC accuracy, correct physicians' interpretation, and family acceptance of the apnea test.

The definition of death used in the recommendations does not include the absence of residual hormonal function or temperature regulation. Investigations comparing causes and mechanisms of death, imaging, and ancillary testing results between patients with and without these preserved functions may be illuminating.

Death determination by circulatory criteria

With a brain-based definition of death, meeting the circulatory criteria implies that cessation of brain perfusion and hence function have occurred. Plourde *et al.* recently highlighted that while brain function requires perfusion and brain perfusion requires flow, the presence of detectable brain blood flow or perfusion does not imply brain function.¹⁰ The lower limits of regional brain blood flow and perfusion required to generate brain function are poorly understood. We advocate for research focusing on the assessment of brain function with the ultimate goal of developing an ideal noninvasive method to

measure the absence of brain function rather than surrogate flow and perfusion.

The minimal pulse pressures (as an indirect measure of cardiac output) generating brain flow, perfusion, and function are unknown. Future large-scale studies that focus on brain function in relation to arterial pulse pressures will advance this field. The use of specific neuromonitoring during DCC needs to be further evaluated in the context of a new brain-based definition. The required interval of time after injury or return to spontaneous circulation after cardiac arrest to ensure that loss of brain function is permanent needs more direct evidence.

Whenever possible, invasive blood pressure monitoring is employed to assess the cessation of circulation. More research is also required to identify noninvasive monitoring devices with high sensitivity and specificity profiles for accurate pulselessness detection or absence of cerebral function to replace the arterial line when unavailable or precluded, as may be with children and medical aid in dying (MAID) patients.

Ancillary testing

The available evidence on ancillary tests is limited. Most studies of their diagnostic accuracy have a moderate to high risk of bias. They mostly assess brain blood flow as surrogates of function as a whole or in limited brain areas. The timely correlation between the absence of brain flow as detected on ancillary tests and the actual cessation of brain function should be investigated. The reliability and cost-effectiveness of ancillary tests for DNC merit more investigation. Their interpretation by nonexperts is scarcely studied, limiting their applicability in all-hospital settings. A challenge for all comparative research is what should be considered the gold standard for comparison.

While the new Canadian Guidelines do not accept primary infratentorial brain injury as fulfilling the definition of death, guidelines from other countries do; studies of the potential for covert consciousness in these conditions have not been explored. An ideal ancillary test would measure brain function and not blood flow or perfusion as a surrogate. Furthermore, this modality should pay concurrent attention to the cerebrum and the brainstem without being susceptible to confounding factors. Qualitative research exploring family members' perspectives on ancillary tests will inform about their potential influence on understanding and acceptance of DNC.

Specific populations

Despite progress in research surrounding the determination of death, there are universal gaps in under-represented populations, including neonates, children, various cultural groups, and patients seeking MAID. A particular focus on people from rights-bearing indigenous nations is missing. Inclusiveness is essential for exploring physiologic, social, and ethical considerations in this research field. As for other under-represented populations, more investigation is required about indigenous nations' perspectives on death determination, dying, and organ donation processes. For example, the recommendation about the duration of the hands-off period between circulatory arrest and DCC⁶ relies essentially on studies performed with adults undergoing withdrawal of life-sustaining measures (WLSM) in intensive care settings.^{11,12} The external validity of these data to other specific populations is unknown. Particular considerations for neonatal and pediatric patients during DNC also require further exploration. While a second DNC exam is suggested in these populations, the level of discrepancy between successive DNC examinations is not known for infants with open fontanelles. Though this new guideline offers recommendations, high-quality evidence about the validity

of the various ancillary testing modalities is lacking among different target population subgroups, including neonatal and pediatric ages.

Patient and family involvement

Patient-centred and family-centred care in the period of death is a current focus of qualitative research, with the recent publication of studies about patients' relatives' experiences and perspectives on dying and organ donation processes.^{13–16} Specifically, family experience with research on dying patients has been explored.¹⁷ A scoping review has evaluated the general public's understanding of the definition and determination of death globally.¹⁸ Nevertheless, multiple knowledge gaps persist regarding families' perspectives about their relative's death. Qualitative studies about families' experiences and perceptions of WLSM, DCC, and DNC processes are key elements of knowledge to gather concerning end-of-life and organ donation. The involvement of patients, donors, and families must be ubiquitous in sensitive areas of organ donation and more specifically to death determination. Their participation needs to begin at the development stage of inquiry to help develop research questions that are meaningful and relevant. Developing processes, structures, and support for these partners to promote meaningful contribution and recognition is imperative to prevent tokenism. Recognizing that participation in a research project is an immense commitment, a large pool of partners needs to be fostered so that the same individuals are not overburdened by multiple projects. Exploring the impact of financial incentives for participation is needed.

Systematic data registries

A systematic method for the collection, storage, and retrieval of data related to the determination of death in various contexts (WLSM, organ donation processes, MAID) is needed. This could include clinical and beat-to-beat monitored data in intensive care unit settings. For instance, advances to current practice would be facilitated with more specific longitudinal data pertaining to WLSM, including the timing of death, the methods of death declaration, and the incidence of spontaneous resumption of circulation. Similarly, routinely collected and accessible data on the death determination process, including the neurologic examination results, use of sedatives, concurrent medical conditions, and completed ancillary tests, would be necessary. To understand the potential hierarchy among brainstem reflexes and their evolution, we advocate for a standardized data collection of all aspects of the DNC examination (serial brainstem reflex testing, etc.)

Table 4 Suggestions to address knowledge gaps about the dying process, the definition of death, and the determination of death

- 4.1. Further engagement with the public, including information about how death is determined in Canada
- 4.2. Support infrastructure and specific funding policies for research on dying processes, death determination, and organ donation
- 4.3. Centralized REB for donation and death thematic
- 4.4. Research initiatives about indigenous Canadian populations
- 4.5. Research initiatives about underrepresented populations and minority groups
- 4.6. Systematic registry of apnea tests
- 4.7. Systematic registry of ancillary tests
- 4.8. Systematic registry of WLSM practices and outcomes
- 4.9. Systematic registry of neurologic clinical and brainstem assessments after devastating brain injury with high risk for mortality

REB = Research Ethics Board; WLSM = withdrawal of life-sustaining measures

during the management of devastating brain injury until the determination of death. Table 4 presents some suggestions for common initiatives to increase knowledge about the process of dying, the definition of death, and the determination of death.

Feasibility of research

Canadian researchers are frontrunners in the field of end-of-life physiology as well as research on patients', their families', and the general population's experiences and perspectives on end-of-life concepts and processes; they have embarked on explorations across the entire donation process, from donor registration, consent processes, and family perceptions to death determination and donor management. Important Canadian research programs are helping strengthen prospective objective evidence to support DNC and DCC.^{11,12,19–23}

Patients, families, and donors are supportive of research and keen to participate in developing research questions and protocols.^{17,24} Research in death determination is unique and often ethically challenging, especially since many of the concepts apply specifically to organ donation policy and practice. The major ethical considerations are discussed in a specific reflection paper.²⁵ Every knowledge gap we identify in the following paragraphs would imply conducting research on these populations, and particular attention must be paid to ethical concerns. The timing of a study intervention or data collection with respect to the actual DNC gives rise to different implications regarding research participant protection. Research ethics boards (REB) may struggle to understand the issues and find reviews of proposals challenging. A centralized REB for studies related to death and organ donation may streamline the review process while ensuring integrity and high ethical standards for research in this area.

Research in the field of death determination as it relates to organ donation is still emerging and is possible in Canada thanks to the active involvement of partners like provincial organ donor organizations, university and hospital research institutes, the Canadian Blood Services, Health Canada, the Canadian Institutes of Health Research, and the Canadian Donation and Transplantation Research Program. The support, the recognition of the research efforts, and the funding these institutions provide to researchers are essential to make progress and ensure high-quality methodology. We advocate for developing sustainable infrastructure and funding policies to promote research projects in this field. We also strongly call for increased financial support opportunities for research projects about death determination, the physiology of the dying process, patients' and their families' experiences surrounding end-of-life care, along with family members' bereavement, post-hospital needs, and support.

Conclusion

Substantive knowledge gaps have been identified while generating the clinical practice guideline recommendations for determining death after the arrest of circulation and neurologic function according to a brain-based definition of death. These guidelines have highlighted the need for better direct evidence to inform DCC and DNC practices. Despite questioning about death being ubiquitous in the arts, mass media, and spiritual and philosophical discourses, medical research has left many questions unanswered. Canadian researchers are leaders in the science of organ donation and end-of-life physiology. Therefore, we strongly encourage new and established researchers to address these questions and advocate for innovative research projects and funding to fill these knowledge gaps.

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