Deceased organ and tissue donation after medical assistance in dying and other conscious and competent donors: guidance for policy

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The planning committee would also like to acknowledge all individuals who contemplate organ donation as part of their end-of-life care after making the decision for medical assistance in dying or withdrawal of life-sustaining measures.

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Foreword

In Canada, organ donation from deceased donors is a common practice that saves or improves the lives of more than 2,000 Canadians every year, accounting for more than 3 out of 4 transplanted organs.[1] Deceased donation is permitted following either neurological or circulatory determination of death. Donation following neurological determination of death (DNDD) is more common in Canada, but rates of DNDD have remained largely stable over the past decade. Donation following circulatory determination of death (DCDD) was historically considered more controversial than DNDD, but DCDD has become increasingly common, accounting for 23 per cent of all organs donated in Canada in 2016.[1] The practice of DCDD is also evolving; the DCDD guidelines developed in 2005 addressed the conventional scenario of an unconscious, incapable, critically ill patient who was not expected to survive after the withdrawal of life-sustaining measures (WLSM).[2]

However, two recent developments have led to scenarios that raise practical and ethical issues that are not clearly addressed in the 2006 guideline. First, as a result of the Supreme Court of Canada's decision in the case of *Carter vs. Canada*[3], and the passing of Bill C-14 by the Canadian parliament[3,4] and Bill 52 in Quebec[5], eligible Canadian patients suffering from terminal illnesses may now seek medical assistance in dying (MAID) as a means of ending their lives under the supervision of a medical or nurse practitioner. Second, there has been an anecdotal increase in requests for organ donation by patients with progressive neuromuscular diseases who are dependent on mechanical ventilation (invasive or non-invasive) and who have made the decision to withdraw life-sustaining measures. These two scenarios differ from the conventional DCDD scenario in that the donors are conscious and competent and, therefore, able to give first-person consent for both the decision to withdraw life-sustaining measures and the decision to donate their organs. These scenarios can be challenging emotionally and morally for health care teams and they can raise unprecedented ethical and practical challenges for patients, families, professionals, institutions, and society.

Prompted by individual cases and requests from patients, Canadian practitioners have requested guidance for policy development to manage organ donation in these conscious competent patients. In response to this request, Canadian Blood Services, in consultation with the Canadian Neurological Sciences Federation and in collaboration with the Canadian Critical Care Society, the Canadian Society of Transplantation, and the Canadian Association of Critical Care Nurses, convened to provide bioethical, legal, and clinical guidance for guidance about managing deceased organ and tissue donation for conscious competent patients.

Executive Summary

Purpose and objectives of the workshop

Canadian Blood Services hosted a forum in Toronto on May 15 and 16, 2017. The two-day forum brought together medical, legal, and bioethics experts, as well as patients, from across Canada. The goal of this forum was to develop expert guidance for clinicians, donation program/organ donation organization (ODO) administrators, end-of-life (EOL) care experts, MAID providers and policy makers regarding organ and tissue donation from a conscious and competent patient. The forum objectives were to:

1) Analyze organ and tissue donation in the conscious competent patient from legal, medical, and ethical perspectives.
2) Develop and publish expert guidance for offering organ and tissue donation to patients who have made a decision that will lead to imminent death:
    a. Conscious competent patients who have chosen to withdraw mechanical ventilation (includes invasive and non-invasive forms of ventilation).
    b. Conscious competent patients who have chosen to withdraw extracorporeal support including ECMO (extracorporeal membrane oxygenation) and/or other mechanical circulatory support.
    c. Eligible patients who have requested MAID (as defined as death by injection).
3) Develop a knowledge translation strategy that includes all relevant stakeholders.
4) Identify questions for research.

Summary of recommendations

Deceased organ donation in conscious and competent patients

1. Medically suitable, conscious and competent patients who provide first person consent to end-of-life procedures should be given the opportunity to donate organs and tissues. Patients who seek MAID or WLSM should not be prohibited from donating organs and tissues.

2. Before consenting to WLSM or MAID, patients should carefully consider all end-of-life options with their physician or health care professional.

Referral to an organ donation organization

3. Referral to the organ donation organization should occur as soon as is practical after the decision to proceed with WLSM or determination of eligibility for MAID. Preliminary evaluation of the patient's eligibility to donate should be performed prior to the donation approach, if possible. This avoids the potential distress of making a request or obtaining consent for donation only to have to inform the patient that they are medically or logistically ineligible.

Conversations about donation

4. The decision to proceed with MAID or WLSM must be separate from, and must precede, the decision to donate.
5. Treating physicians, MAID providers, and MAID assessors should be educated on how to respond to inquiries concerning organ donation. This should include how the decision to donate may affect the end-of-life care process and options, and when to refer patients to the organ donation organization. The organ donation organizations should develop checklists or discussion guides to facilitate donation conversations to ensure patients are consistently well informed.
6. All eligible, medically suitable patients should be given an opportunity to consider organ and tissue donation, consistent with provincial or territorial required referral legislation, regional policy, and ethical principles of respect for autonomy and self-determination. However, this must be reconciled with regional values and health care culture. Initially, some jurisdictions might prefer to begin with systems that respond only to patient-initiated requests.
7. Donation coordinators will have to tailor their conversations to ensure the patient remains the centre of the MAID or WLSM and organ donation process, to ensure patient autonomy.
8. When an approach is to be made, discussions should happen early to allow individuals time to consider the options, ask questions, and to plan accordingly.
9. Patients and their families should be provided with standardized information resources, such as online material or pamphlets to help guide responses to donation inquiries. The decision to proceed with MAID or WLSM must precede discussions about donation.

Consent

10. The patient must have the ability to provide first-person consent to MAID or WLSM as well as to organ and or tissue donation.
11. Physicians, MAID assessors, and WLSM or MAID providers should be cognizant of the risk of coercion or undue influence on patients to donate their organs; however, the patient's altruistic intentions should not be discouraged.
12. Donation discussions must respect patient autonomy and first-person consent should be obtained and upheld. Although it is welcomed and encouraged that family members are included in donation conversations, consent must be obtained from the patient and conversations should be focused on them.
13. The individual should be informed and understand that they may withdraw consent for MAID or donation at any time, and that withdrawal of consent for donation does not affect their consent for, or access to, MAID or WLSM.
14. The donation team should make every effort to resolve conflict, through dialogue, between the patient's expressed wishes to donate and a family's disagreement. First-person consent should direct all subsequent decisions unless consent was revoked.
15. If a conscious and competent patient provides first-person consent to donate after WLSM but subsequently loses decisional capacity, there is a strong case for proceeding with donation after WLSM because the patient was adequately informed about the decision by a trained donation expert and gave consent in the context of their illness

and an anticipated imminent death. However, if a patient loses capacity prior to the MAID procedure, then MAID procedures cannot be carried out.

16. The donation team must understand and abide by the laws and policies of their jurisdiction with respect to reporting of MAID deaths (e.g. coroner, special committee). To facilitate donation, these parties should be contacted prior to the MAID procedure, in accordance with the current laws and policies.

Donor testing and evaluation

17. Primary care physicians, and staff or organ donation organizations, MAID providers and transplant teams should work to minimize the impact and inconvenience to the patient of donating their organs. This could include scheduling home visits for blood draws and coordinating investigations (e.g. x-rays, ultrasound) to minimize hospital visits and inconvenience to the individual.

18. Transplant teams and surgeons should work with the donation team to determine the minimum necessary investigations, to avoid the burden of excessive assessments and testing.

19. Donor teams should routinely discuss the potential impact of unanticipated results from the donor investigations, including previously undiagnosed infectious diseases, and their impact on public health reporting and contact tracing.

MAID procedures

20. Consent for MAID must be reaffirmed prior to the MAID procedure. The health care team or MAID provider should reaffirm consent prior to relocation to the hospital and prior to beginning any antemortem interventions for the purposes of facilitating donation. This may reduce the momentum of the donation process and reduce the potential for patients to feel pressured to continue with MAID in the interest of ensuring organ donation.

Determination of death

21. The dead donor rule must always be respected. Vital organs can only be procured only from a donor who is already deceased; the act of procurement cannot be the immediate cause of death.

22. For determination of death, absence of a palpable pulse alone, is not sufficient. If arterial monitoring is not available, alternate means of determining absence of anterograde circulation should be used in conjunction with absence of a palpable pulse, such as a carotid perfusion ultrasound, Doppler monitoring, aortic valve ultrasound or an isoelectric EKG to determine asystole.

23. As with all cases of DCDD, death should be confirmed by a second physician after a 5-minute ‘no touch’ period of continuous observation during which time no donor-based interventions are permitted.

Protection for patients

Separation of decisions

24. To avoid any real or perceived conflict of commitment, health care practitioners should separate the decision regarding WLSM or MAID from discussions concerning donation. Providers who are assessing eligibility for MAID should not be involved in donation discussions. Discussions concerning donation should happen only after WLSM decisions are made, or patients have been found eligible for MAID by 2 independent assessments.

25. The primary health care team should acknowledge patient inquiries concerning donation that are made prior to a decision to proceed with MAID or WLSM. General information on deceased organ and tissue donation may be provided. However, specific discussion and decisions pertaining to donation should wait until the decision to proceed with MAID or WLSM has been finalized.

26. Patients may wish to postpone their MAID procedure, owing to a temporary improvement in their health or an event they wish to experience prior to their death. The freedom of the patient to postpone their MAID procedure must be reinforced and preserved and every effort should be made to honor their wishes to donate their organs should their MAID procedure be rescheduled.

Directed and conditional donation

27. No restrictions should be placed on potential organ recipients. Directed deceased donation (direction of a patient's organs to a specific recipient) or conditional donation (e.g. organs will be donated only if the patient can place conditions on what social groups may or may not access them) from patients considering MAID or WLSM should be neither offered nor encouraged.

28. Living donation prior to death from patients considering MAID or WLSM should be neither offered nor encouraged.

29. Should a patient insist on directed deceased donation or living donation prior to death, the request should be considered on a case-by-case basis.

Separation of roles

30. Consistent with current guidelines and practice regarding DCDD, separation should be maintained between the EOL care, donation, and transplant teams. Surgical recovery and transplant teams should not be involved in the patient's end-of-life care or MAID or WLSM procedure. The only exception is insofar as they may provide guidance for minimal requirements for donor investigations or premortem interventions.

31. Patients who wish to donate their organs after MAID or WLSM, but who request that their decision to pursue MAID/WLSM remain confidential, should be informed of the risk that their family members may discover incisions associated with surgical retrieval of organs. They should be encouraged to disclose their decision to family members; however, there is no obligation to stop the donation process should the patient wish to maintain the confidentiality of their MAID or WLSM procedure.

32. That an organ donor received MAID should not be disclosed to the potential recipient during allocation; however, medically relevant information regarding their underlying disease may be disclosed according to guidelines for exceptional distribution, where applicable.

Supports for patients and families

33. Specially trained professionals, such as donation physicians and coordinators, patient navigators, or social workers, must be available to answer the patient's questions and facilitate the coordination of their MAID or WLSM and donation. This may take place over a period of many weeks. The patient and their family must be provided with specific instructions on how to access these resources.

34. Support should be available in an optimally convenient location and setting for the patient, such as home visits or coordination with visits to clinics. For patients in remote locations, video-based technologies may be of assistance.

35. The donation team should work with the patient, their family, and the MAID or WLSM provider to develop a plan and best possible options for the MAID or WLSM procedure that accommodates the wishes of the patient, preserving the opportunity to donate and reconciling coordination of hospital logistics.

36. Ongoing access to support for patients and their families is critical. Despite patient consent, donation might not proceed due to failure to find a suitable recipient, deterioration of health that compromises medical eligibility to donate, surgical findings during organ recovery, or withdrawal of consent by the patient. These patients and their families must continue to receive support even if donation does not proceed.

37. Continued support must be available to family members after the patient's death. Processes need to be developed to ensure families are given the opportunity to provide feedback on their experience, which may help with their grieving process and may help inform quality improvement measures.

Amyotrophic lateral sclerosis (ALS) and neurodegenerative diseases

38. People with ALS and patients with other non-transmissible neurodegenerative diseases should be offered the opportunity to donate organs after their death.

39. ODOs should exercise caution regarding allocation of organs from donors with undiagnosed or rapidly progressive neurodegenerative diseases, as these may pose elevated risks to recipients. Organ allocation in this context should follow existing exceptional distribution policies and practices.

40. Transplant professionals must balance the benefits of the transplant against any potential for harm of receiving a transplant of an organ from a donor with a neurological illness. Transplant professionals must use their discretion to help the transplant candidate navigate the decision. The surgeon may wish to consult the donor's neurologist to help inform their advice to the transplant candidate.

41. All cases of ALS or other neurodegenerative diseases that arise in transplant recipients should be reported to Health Canada to determine potential associations with donor illness and baseline risk of neurodegenerative illness in transplant recipients (e.g. whether transplant recipients, in general, have rates of ALS that differ from the general population).

42. Physicians who follow organ recipients should be: aware that the donation was by a patient with neurodegenerative disease such as ALS, aware of theoretical transmission risk of neurodegenerative diseases, and cognizant of symptoms or complaints that warrant further investigation by a neurologist to determine if a neurodegenerative disease is present.

43. Active monitoring (i.e., regular visits to a neurologist) is NOT recommended for transplant recipients who have received an organ from a donor with a neurodegenerative disease. Neurological monitoring would impose a substantial burden on the recipient and present no benefit to the recipient, particularly as there is currently no value in early detection of these illnesses.

44. Information resources should be available for transplant candidates and for transplant professionals to help with the decision regarding whether to accept or refuse an organ for transplant. A means of obtaining a consult from a specialist neurologist in neurodegeneration may also be useful in helping the potential recipient make an informed decision. This information should also be available to ODOs and the donation professionals responsible for assessing the eligibility of the patient who is considering donation.

Health care professionals

45. Health care professionals may exercise a conscientious objection to MAID or WLSM specifically, but they should strive to accommodate the wishes of the donor by ensuring that their objection to MAID or WLSM does not impede the ability of the patient to donate.

46. Health care professionals should act in accordance with provincial and territorial requirements as well as professional and regulatory college requirements for effective referral.

47. Health care professionals responsible for the care of conscious, competent patients who have requested WLSM or MAID and donation should be briefed so they are familiar with the patient's end-of-life plan and relevant policies and procedures.

48. Debriefing after the procedure (i.e., MAID or WLSM with or without donation) should be offered every time to all members of the health care team who participated. Debriefing by an external resource may be beneficial so that team members feel comfortable sharing their experience.

49. Psychological support, such as that offered through employee assistance plans (EAP), should be accessed when required. Staff of employee assistance plans may benefit from additional training and education regarding MAID with or without donation to adequately meet the needs of these health care professionals.

50. Hospitals must ensure that staff are available who are willing and able to honor the patient's wishes to donate after their death or have an effective referral plan in place.

51. Participation of health care professionals in MAID and in organ donation by patients who received MAID should be voluntary, when possible, without interfering with the patient's access to care. The health care team should be well informed and well briefed so that they understand the patient's wishes and the outcome they are working towards as well as relevant policies and procedures.

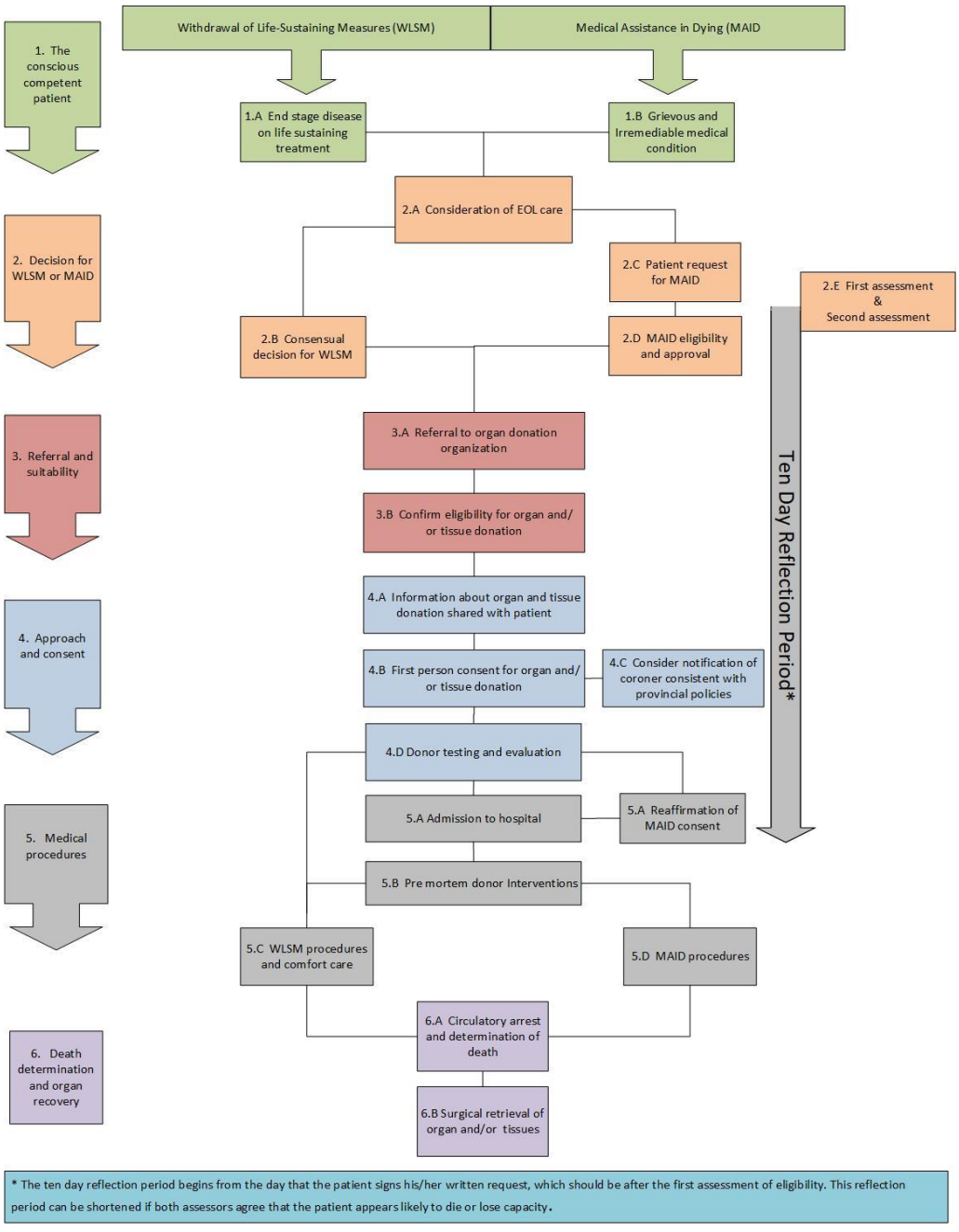
Reporting

52. Clinicians must be aware of the reporting and documentation requirements for MAID and WLSM and for donation in their jurisdiction.

53. Records pertaining to organ donation after MAID, as well as donation and transplant outcomes, should be reported federally and be accessible to clinicians, researchers, and administrators. Transplant outcomes should be easily cross-referenced with the underlying illness of the MAID donor.

Figure 1 outlines the clinical pathway for organ donation in conscious competent patients.

Figure 1. The Clinical Pathway for Organ Donation in Conscious Competent Patients



Overview

A. Workshop Overview

In order to gather perspectives and insight from multiple stakeholders across Canada, Canadian Blood Services hosted a workshop in Toronto on May 15 and 16, 2017. The two-day forum brought together medical, legal, and bioethics experts, as well as patients, from across Canada. The goal of this forum was to develop expert guidance for clinicians, donation program/organ donation organization (ODO) administrators, end-of-life (EOL) care experts, MAID providers and policy makers regarding organ and tissue donation from a conscious and competent patient. The workshop agenda and background documents are provided in Appendices 3 to 8.

Purpose and objectives

1) Analyze organ and tissue donation in the conscious competent patient from legal, medical, and ethical perspectives.
2) Develop and publish expert guidance for offering organ and tissue donation to patients who have made a decision that will lead to imminent death:
    a. Conscious competent patients who have chosen to withdraw mechanical ventilation (includes invasive and non-invasive mechanical ventilation).
    b. Conscious competent patients who have chosen to withdraw extracorporeal support including ECMO and/or other mechanical circulatory support.
    c. Eligible patients who have requested MAID.
3) Develop a knowledge translation strategy that includes all relevant stakeholders.
4) Identify questions for research.

Planning committee and key contributors

The planning committee members are noted below. See Appendix 2 for a full list of workshop participants.

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Stakeholders

Stakeholders are individuals, groups, and organizations with a significant stake in the purpose, objectives, and outcomes of this process. It is important to consider the impact of recommendations on several stakeholder constituencies. For the purposes of the project, we considered the potential impacts on the following stakeholder groups (listed in alphabetical order):

- Coroners and Medical Examiners
- Health authorities, governments, and policy-makers
- Health care professionals and administrators who are involved in critical care, emergency medicine, neurology
- Health care professionals who care for dying patients and administrators with responsibility for the program
- Institutions, e.g., hospitals, health care regions
- MAID providers and assessors
- Organ Donation Organizations (ODO), donation personnel, health care professionals and administrators who may take part in the donation process
- Partners in the leading practice development process
- Patients and society-at-large
- Research funders and organizations

In scope

1) Controlled DCDD in patients with the following features:
    a. Awake, conscious and competent;
    b. Adults or mature minors;
    c. Ability to provide first-person informed consent to make their own treatment and/or end-of-life (EOL) decisions; and
    d. Have chosen an EOL care intervention that would lead to imminent death:
        i. Withdrawal of life-sustaining measures, or
        ii. Medical assistance in dying consistent with existing or evolving federal and provincial legislation.
2) Pathogenesis and transmissibility of illnesses that would make a patient eligible for MAID or WLSM with influence on medical eligibility for organ donation.
3) Ethical implications and potential outcomes of allowing organ and tissue donation by these patients.

4) Education and training requirements for health care professionals.
5) Public and patient awareness.

Out of scope

1) Ethics of MAID or WLSM
2) Best practices for MAID or WLSM independent of organ and tissue donation.
3) Donation by euthanasia (i.e. organ donation that does not adhere to the dead donor rule).
4) Living organ donation.

Assumptions and key considerations

1) Organ donation and transplantation is broadly accepted and supported by workshop participants and the Canadian public; organ donation and transplantation benefits society.
2) Current Canadian controlled DCDD guidelines[2] do not sufficiently address the management of conscious competent patients.
3) Requests for organ and tissue donation by conscious competent patients requires clinical, bioethical and legal guidance.
4) Optimal care of the dying patient is the priority of health care workers.
5) Decisions made via first person informed consent are the highest standard of decision making for treatment and EOL care.
6) Consistent with existing laws and practices, deceased organ donation must adhere to the dead donor rule.
7) Professional integrity should always be maintained. Health care providers are guided by their own values and beliefs as well as professional values and practice standards.

B. Workshop Process

Prior to the workshop, the planning committee commissioned a survey, performed literature searches, and developed background documents to guide and support discussion on the following topics:

1) Canadian attitudes towards organ and tissue donation by conscious competent patients; Appendix 3 - IPSOS Public Survey
2) Requests for organ donation by conscious, competent patients; Appendix 4 – Gruben, Yazdami, and Goldberg
3) Pathogenesis and potential transmissibility of amyotrophic lateral sclerosis; Appendix 5 - Shoesmith
4) Conscientious objection as it relates to donation after MAID; Appendix 6 – Buchman and Gruben

The workshop was structured around plenary presentations by Canadian and international clinicians, organ donation and transplantation ethicists and legal experts, a coroner, and patient partners. See Appendix 7 for full agenda.

Attendees were divided into smaller groups throughout the meeting to discuss and make recommendations regarding specific challenge questions that were informed by fact sheets and expert presentations. See Appendix 8 for fact sheets and challenge questions. Key points and conclusions from these groups were then shared in plenary.

Withdrawal of life-sustaining measures and controlled donation after circulatory determination of death

The majority of controlled DCDD cases occur after acute devastating brain injury. In such cases, the patient is unconscious and, thus, not competent to participate in their own EOL care decisions. While intent to donate decisions may have been registered or indicated in advance, decisions concerning EOL care, WLSM and donation are made by the patient's substitute decision maker (SDM) in consultation with the health care team.

There are other groups of patients with illnesses that are incurable and terminal but are not associated with devastating brain injury. These patients may be conscious, competent, and capable of actively participating in decisions about their EOL care, including decisions for WLSM or MAID, as well as consenting to organ donation.

WLSM is the most common event preceding death in Canadian intensive care units[6] and is a step in the clinical pathway of nearly all DCDD organ donors. The decision by the patient's SDM to withdraw treatment is based on poor prognosis, concern for the patient's suffering, and/or poor future quality of life[7] and should be consistent with the patient's values and/or prior expressed wishes.

While many of these patients may be eligible to donate organs, there are several barriers to organ donation in this population. These include a failure to identify a potential donor; failures on behalf of the health care team to approach SDMs for authorization for donation, refusal of

authorization by the family or SDM, death not occurring in a specified time period that allows suitable organs for transplantation and lack of resources for surgical retrieval of organs and transplantation.[8] Only about 2 per cent of in-hospital deaths may be considered potential donors and, of these, only one in six will actually donate an organ.[8]

Medical assistance in dying

The legal landscape around MAID has evolved rapidly in Canada following the Supreme Court decision that prohibitions in the *Criminal Code of Canada* were unconstitutional and the passing of legislation, first in Quebec[5] and then by the Federal Government of Canada[4], permitting MAID under certain circumstances. Specifically, the patient must have a "grievous and irremediable medical condition", defined by the following criteria:

a) they have a serious and incurable illness, disease or disability;
b) they are in an advanced state of irreversible decline in capability;
c) that illness, disease or disability or that state of decline causes them enduring physical or psychological suffering that is intolerable to them and that cannot be relieved under conditions that they consider acceptable; and
d) their natural death has become reasonably foreseeable, taking into account all of their medical circumstances, without a prognosis necessarily having been made as to the specific length of time that they have remaining.[1]

Early demographics for MAID

Statistics for MAID cases in Canada at the time this forum occurred were available from the period July 1, 2016 to Dec. 31, 2016 (Dec. 10, 2015 to Dec. 31, 2016 for Quebec) and are summarized in Table 1. Nearly half of all the assisted deaths – 463 – took place in Quebec, where a separate end-of-life law took effect on Dec. 10, 2015, six months before the federal law came into effect. Compared with other countries[9-11], the early experience in Canada is notable for an underrepresentation of cancer patients and a higher incidence in patients with chronic neurological conditions. Accordingly, Canada has the highest rates of multiple sclerosis in the world.[12]

It is unclear if this early trend of MAID in Canadian patients with chronic neurological conditions will continue, as it may be due to an initial overrepresentation of patients with chronic (non-cancer) illnesses who were waiting for MAID to become available to them. Patients seeking MAID for terminal cancer are often not medically eligible to become donors; therefore, those who comprise the pool of potential donors among MAID patients have underlying illnesses within the other categories.

[1] s. 241.2(2) of the Criminal Code of Canada.

Table 1. Demographics of MAID

Cause of Death	Netherlands[9]	Belgium[10]	US*[11]	Canada
Cancer	79%	80%	80%	57%
Cardiovascular	4%	4%	3%	11%
Respiratory	16%	5%	4%	
Neurological		7%	8%	23%
"Other"		4%	5%	8%
Annual Cases (cases/million)	3800 (224)	2800 (247)	100 (0.3)	970 (27)

* Euthanasia is illegal in the United States and assisted suicide is only permitted in some states, therefore organ donation is not possible.

Rationale for donation after MAID and WLSM

A review of the literature found support for offering the opportunity to donate organs after death to patients seeking MAID or WLSM, while also highlighting some ethical concerns as illustrated below in Table 2.

Table 2. Rationales for and against deceased organ donation following MAID/WLSM (adapted from Shaw DM[13])

Rationale in support of organ donation following MAID/WLSM

• Could increase the number of organs available for donation[14-24]
  ○ Organs may be of better quality than conventional DCDD[20]
• Respect for individual autonomy and self-determination[14, 16, 17, 25-28]
• Personal benefit to the donor, whose own death may easier to bear if he or she knows that death will save or improve the life of another[16, 28]
  ○ Likewise, benefit to family by providing increased solace or comfort during their grieving
• Cost-effectiveness as a factor in favor of permitting organ donation in these circumstances [16, 24]
• May increase public acceptance of assisted dying[24]

Concerns about organ donation following MAID/WLSM
• May unduly pressure patients — a person who may not otherwise opt for MAID might choose to die to donate his or her organs to help others[16] • Permitting organ donation following WLSM or MAID could undermine public trust in the organ donation system because "physicians would be tempted to be deliberately pessimistic about the patient's prognosis to enhance the patient decision to request for withdrawal of treatment"[25]

Public perception

In September 2016, Canadian Blood Services commissioned IPSOS to conduct a survey of Canadian adults (*n* = 1,006) concerning their attitudes towards organ donation in competent conscious patients:

- 92 per cent approve of people donating their organs at the time of their death
- Strong support for conscious competent patients donating their organs after WLSM (87%) or MAID (80%)
    - Significantly more oppose donation after MAID (12%) than after WLSM (6%)
- Concerns of those opposed to donation after WLSM/MAID include:
    - Transmission of illness (48%)
    - Pressure on vulnerable patients to choose WLSM or MAID sooner than they may have otherwise (46%)
    - Pressure on vulnerable persons to donate their organs (43%)
- 80 per cent agree donation should be discussed with all patients regardless of illness or EOL decisions
- 83 per cent agree that the decision to donate organs should be confirmed prior to EOL care administration
    - 53 per cent agree that donation should be discussed AFTER a decision has been made regarding EOL
- 25 per cent were undecided whether they would receive an organ from a donor following WLSM or MAID

These findings show that Canadians broadly support that conscious competent patients should be offered the opportunity to donate after MAID or WLSM; however, a minority of respondents were opposed to donation after MAID or WLSM citing concerns about transmission of illness to the recipient and pressure or coercion of the donating individual. See Appendix 3 for full report.

Donation after MAID – Early experience in Canada

Ontario, British Columbia and Quebec have the most experience with donation after MAID. As of April 2018, Ontario has performed eight organ donations, British Columbia has performed three, and Quebec has performed four donations. The *Trillium Gift of Life Network Act* in Ontario requires that Trillium Gift of Life (TGLN) be contacted when a patient's death is imminent.[29] This has been interpreted to require routine referral to the ODO of patients accessing MAID.[30] In Quebec, the Commission de l'éthique en science et en technologie (CEST) and Transplant Quebec initially provided conflicting guidance on routine requesting in this context.[14, 31, 32] Transplant Quebec initially discouraged raising donation with patients seeking MAID and, instead, offered donation only when patients make a 'double request', that is for MAID and for organ donation. Transplant Quebec has subsequently changed their policy and is now in agreement with routine requesting.

Anecdotally, some donor coordinators have reported comfort with the patient being able to express their own wishes and provide first person consent concerning donation; however, others have reported considerable emotional strain from these interactions. Transplant physicians and surgeons may have reservations about donation by conscious competent patients in both MAID and WLSM due to ethical concerns. Discomfort or misunderstanding with these circumstances may preclude transplantation.

Another challenge has been performing suitability assessments of potential donors. These tests (e.g. blood work, diagnostic imaging) are normally performed in hospital; however, many conscious competent patients are not hospitalized during this period and may have difficulty travelling for purposes of assessment due to their illness.

The ODOs/donation programs, transplant programs, clinical ethicists and bioethics committees, and clinicians across Canada have initiated work in developing processes to allow conscious competent patients to donate after WLSM or MAID; however, policies concerning eligibility of patients with neurodegenerative illnesses to donate, donor suitability assessments, permissibility of pre-mortem interventions, logistics and methods of death determination, continue to be the subject of discourse and evolving practice.

Donation after euthanasia in Belgium

Belgium legalized euthanasia in 2002, one year after the Netherlands. Patients eligible for euthanasia in Belgium must have a medical condition with constant and unbearable physical or mental pain, which cannot be relieved.[26] Belgian law states: "The patient is an adult or an emancipated minor, capable and conscious at the time of his/her request. The request is made voluntarily, is well thought out and reiterated, and is not the result of outside pressure."

Key differences from Canada's legislation are that Belgium allows euthanasia for patients whose disease is not terminal, including mental illness, and for mature minors.
In Belgium, euthanasia and donation require separate decisions by the patient and are administered by separate health care personnel. Currently, patients are not actively approached as there is a concern of pressure or coercion, but patient-initiated requests are considered. Patient-initiated donation discussions may take place after permission for euthanasia has been granted.

Euthanasia must take place in hospital to allow for donation and the procedure takes place in or near an operating theatre to minimize ischemic time. While every effort is made to accommodate the wishes of the patient and their family and to ensure their comfort, some patients decline to donate, as they prefer to die at home.

Belgium considers donation after euthanasia to be a distinct category of DCDD and all cases in Belgium adhere to the dead donor rule. Procedures are performed by senior medical and nursing staff and their participation is voluntary.

In the donation-after-euthanasia process, heparin is administered directly after the euthanasia medications and death declaration is made by three clinicians. Determination of death is made clinically and there is no invasive monitoring required, preventing the need for invasive arterial blood pressure monitoring. A five-minute 'no touch' period is observed before organ retrieval

begins. In the case of lung donation, the donor is intubated and ventilated following the five-minute 'no touch' period. Since the combination of drugs used for euthanasia is considered by some to be cardiotoxic, heart transplants are not currently possible following euthanasia in Belgium. Patients have expressed a strong desire to be able to donate their heart and there has been discussion, in the interest of patient autonomy, to develop strategies that would enable heart donation.

After the potential donor is assessed and medical eligibility is confirmed, Eurotransplant coordinates allocation four hours before the euthanasia procedure. Transplant centres are informed about the cause of death (i.e. that the donor had died by euthanasia). Eurotransplant allocation may take place between different countries; however, organs will not be allocated to patients in countries that do not accept donors who died by euthanasia. Furthermore, transplant candidates on the waitlist are able to indicate whether they would accept organs from donors after euthanasia. Directed donation is not permitted; however, Eurotransplant may inform transplant centres of a wish to direct donation and they may, at their discretion, allow the request to be facilitated even in cases where they may not have priority on the waitlist. There is no systematic monitoring of recipients for development of transmissible neurological illness in Belgium; however, adverse events are reported.

In 2015, euthanasia accounted for 2,022/110,508 deaths (1.8%) of all deaths in the country and there were eight donors after euthanasia accounting for 2.5 per cent of all deceased organ donors. Approximately 75 per cent of those receiving euthanasia were patients in the terminal phase of malignant disease and therefore not eligible to donate. From 2005-2015, 23 patients, with a mean age of 49.3 years, became organ donors after euthanasia. The underlying illnesses of these patients were neuropsychiatric disorders (*n* = 7), stroke/bleeding (*n* = 4), multiple sclerosis (*n* = 5), other neurodegenerative diseases (*n* = 10), and unbearable pain (*n* = 2). The mean time to circulatory arrest was 7.9 minutes and perfusion was initiated an average of 19.4 minutes after circulatory arrest. [33]

As of 2015, 92 organs (45 kidneys, 21 livers, 16 lungs, 10 islets) were transplanted from 23 donors and the organ quality from post-euthanasia patients has been very good. Some tissues have been transplanted as well; however, concerns over transmission of neurological illness have limited tissue transplantation in some cases.

International policies on donation after medically-assisted death

While medically-assisted death is permitted in several countries now, donation is not possible in all these jurisdictions. See Table 3. In Switzerland, assisted suicide is legal but subsequent donation is not possible, in part, because the procedure is performed by non-physicians and does not occur in hospital. In Luxembourg, the law states that organs may only be procured after cessation of treatment due to extensive damage to the brain; therefore, conscious competent patients cannot consent to deceased donation.

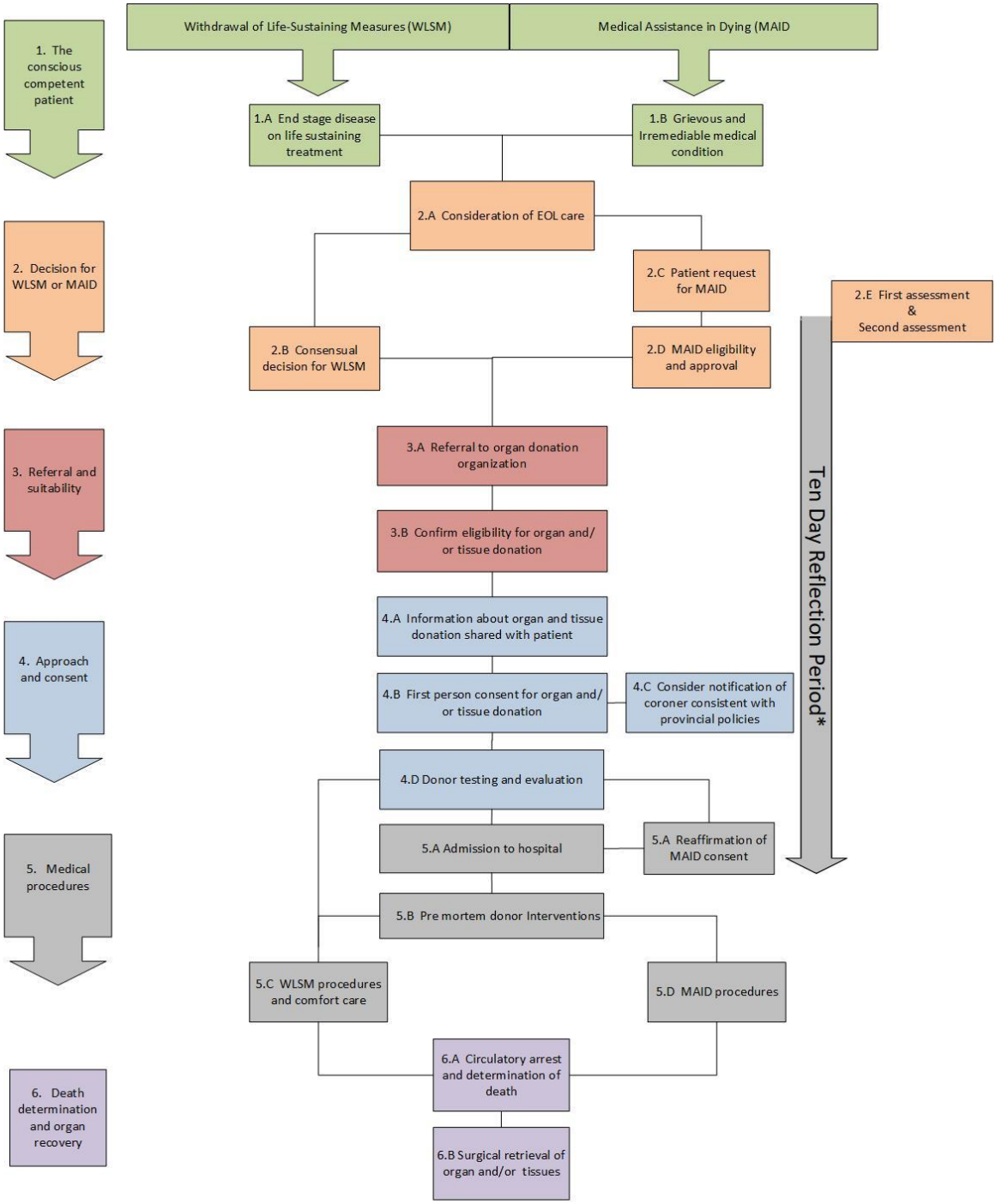
Table 3: Policies on organ donation in countries where medically-assisted death is permitted (adapted from Allard and Fortin, J Med Ethics, 2017)

Country or State	Policy on Organ Donation
Switzerland (assisted suicide by non-physician)	Not possible
Belgium (euthanasia)	Possible at patient request[33]
Netherlands (euthanasia, assisted suicide)	Possible after euthanasia at patient's request; working on an official post euthanasia donation protocol[27]
Luxembourg (euthanasia)	Illegal
Oregon, Washington, Vermont, and Montana (assisted suicide)	Not possible
Ontario, Canada	Routine request
Quebec, Canada	Patient-initiated initially, currently routine request

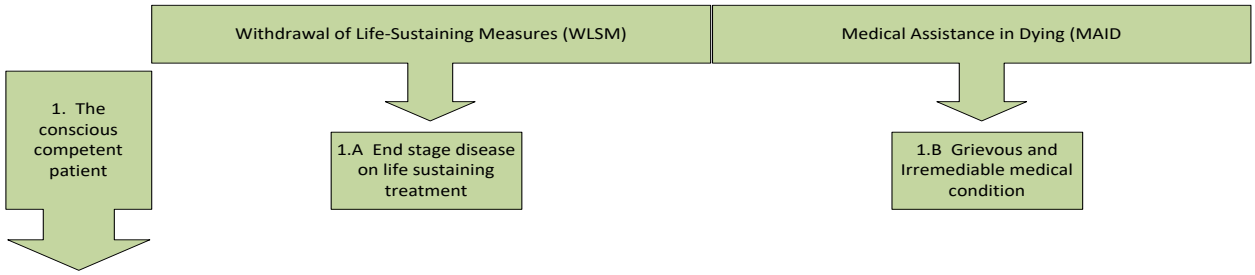
C. Recommendations and Considerations in Relation to the Clinical Pathway

Figure 1 outlines the clinical pathway for organ donation in conscious competent patients.

Figure 1. The Clinical Pathway for Organ Donation in Conscious Competent Patients



1. The conscious competent patient



Conscious competent patients are:

a. Awake, conscious and competent as defined by the laws of their respective jurisdiction;
b. Adults, or mature minors for WLSM (not currently eligible for MAID);
c. Able to provide first-person informed consent to make their own treatment and/or end-of-life (EOL) decisions; and
d. Have chosen an EOL care intervention that would lead to imminent death:
    i. Withdrawal of life-sustaining measures (WLSM),
    ii. Medical Assistance in Dying (MAID) consistent with existing or evolving federal and provincial legislation.

These patients may enter the controlled DCDD pathway via two routes:

1.A) Withdrawal of life-sustaining measures (WLSM), including:

- invasive or non-invasive mechanical breathing support;
- artificial airways;
- cardiovascular support:
    - Extracorporeal membrane oxygenation (ECMO)
    - Left ventricular assist device.

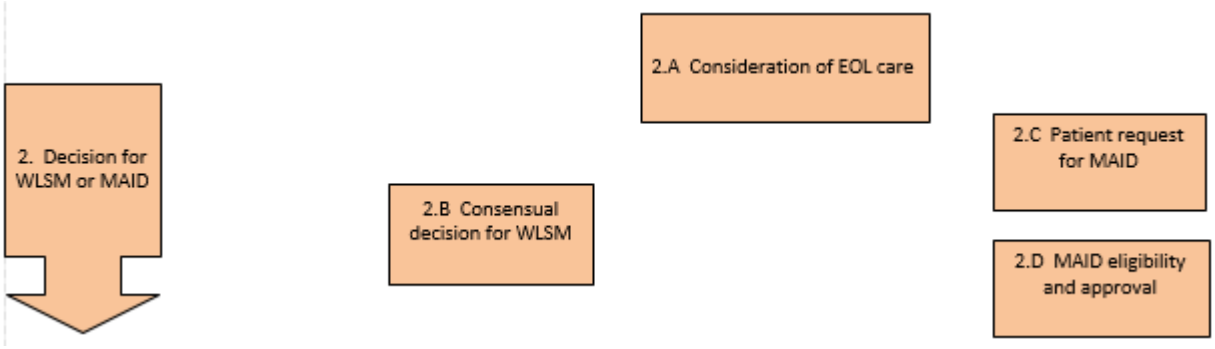
1.B) Medical assistance in dying (MAID)

- In accordance with *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying) S.C. 2016, c. 3*[1] and the relevant provincial legislation.

Stakeholders in this phase of the clinical pathway -

- Patient and family
- Primary care provider or treating team

2. Decision for WLSM or MAID



2.A) Consideration of EOL care

- The patient and his or her primary treating team may discuss and consider options at EOL in a manner that is consistent with the patient's values and with professional standards.
- Conversations should ensure that patients fully understand prognosis and treatment options.
- The health care team (and MAID assessors in the case of MAID) must ensure that the patient has the capacity to make an informed decision.

2.B) Consensual decision for WLSM

- In patients with irrecoverable or life-limiting conditions, refers to the consensual decision (between the health care team and patient) to stop life-sustaining treatments.
- Patients who request WLSM discuss this request with their attending doctor; no formal written request is required.

2.C) Patient request for MAID

- To seek approval for MAID, the patient must make a written request that is signed and dated.
- According to law, the initial assessment should take place before the written request is signed, to ensure that the patient has been informed about the nature of their grievous and irremediable condition and has given informed consent to proceed with MAID. A second, independent MAID assessment can be performed before or after the signed request.
- The request for MAID is subject to a ten-day reflection period prior to the MAID procedure. This reflection period begins when the written request is signed. It may be shortened if both assessors agree that there is an anticipated loss of capacity or natural death is imminent.

Stakeholders in this phase of clinical pathway include:

- Patient and family
- Primary treating team
- MAID assessors

Recommendations: Deceased organ donation in conscious and competent patients

1. ***Medically suitable, conscious and competent patients who provide first person consent to end-of-life procedures should be given the opportunity to donate organs and tissues. Patients who seek MAID or WLSM should not be prohibited from donating organs and tissues.***
2. ***Before consenting to WLSM or MAID, patients should carefully consider all end-of-life options with their physician or health care professional.***

3. Referral and suitability

3.A) Referral to the ODO

- Provincial or territorial ODO is notified; process proceeds according to provincial policies and procedures, usually triggered when death is imminent
- Referral to the ODO is mandatory when death is imminent in British Columbia, Manitoba, Ontario, Quebec; similar legislation in Nova Scotia is awaiting proclamation. Alberta has mandatory consideration after death determination. At the time of this report, Saskatchewan has made it permissive to share personal information of a person whose death is imminent with the ODO for the purposes of determining suitability to donate, but a referral is not mandatory.
- For MAID, provincial procedures may vary from routine referral to patient-initiated referral

3.B) Eligibility for organ/tissue donation

- Patients are assessed for eligibility for organ and tissue donation.
    - Medical eligibility (exclusions due to metastatic cancer, etc.)
    - Logistical eligibility
        - Is deceased donation available in their region?
        - MAID/WLSM must occur in hospital

Stakeholders in this phase of the clinical pathway

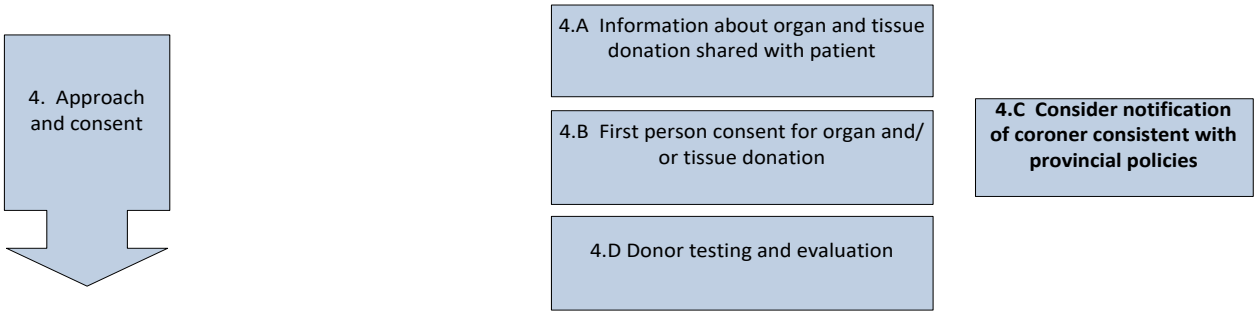
- Primary treating team
- ODO personnel
- MAID assessors/providers

Recommendations: Referral to an organ donation organization

3. ***Referral to the organ donation organization should occur as soon as is practical after the decision to proceed with WLSM or determination of eligibility for MAID.***

Preliminary evaluation of the patient's eligibility to donate should be performed prior to the donation approach, if possible. This avoids the potential distress of making a request or obtaining consent for donation only to have to inform the patient that they are medically or logistically ineligible.

4. Approach and consent



4.A) Information sharing about donation

- If the patient is eligible after assessment in 3.B, information about donation may be shared
- The approach should be made by a trained professional, such as an ODO coordinator
- The patient must be informed of specific requirements for their EOL care to preserve the opportunity for donation, such as:
    - The WLSM or MAID needs to occur in a hospital to facilitate timely access to an operating room for surgical retrieval of organs;
    - Tests or evaluations of organ function may be required prior to the patient's WLSM or MAID (see 4.D below);
    - ODO and transplant surgeons may request pre-mortem interventions, such as heparin, to preserve organ quality during the donation process.

4.B) First-person consent for organ and tissue donation

- Consent for deceased organ donation is obtained directly from the capable conscious competent patient (after MAID approval or WLSM decision).

4.C) Notification of coroner/medical examiner

- Consideration for notification of the coroner according to provincial policy and procedure.

4.D) Donor testing and evaluation

- The ODO and transplant surgeons may request tests, such as:
    - Blood work
    - Imaging (e.g. chest X-ray)
    - Organ function tests

Stakeholders in this phase of clinical pathway:

- Patient and family
- Primary treating team
- ODO personnel, transplant surgeons

Recommendations: Conversations about donation

4. ***The decision to proceed with MAID or WLSM must be separate from, and must precede, the decision to donate.***
5. ***Treating physicians, MAID providers, and MAID assessors should be educated on how to respond to inquiries concerning organ donation. This should include how the decision to donate may affect the end-of-life care process and options, and when to refer patients to the organ donation organization. The organ donation organizations should develop checklists or discussion guides to facilitate donation conversations to ensure patients are consistently well informed.***
6. ***All eligible, medically suitable patients should be given an opportunity to consider organ and tissue donation, consistent with provincial or territorial required referral legislation, regional policy, and ethical principles of respect for autonomy and self-determination. However, this must be reconciled with regional values and health care culture. Initially, some jurisdictions might prefer to begin with systems that respond only to patient-initiated requests.***
7. ***Donation coordinators will have to tailor their conversations to ensure the patient remains the centre of the MAID or WLSM and organ donation process, to ensure patient autonomy.***
8. ***When an approach is to be made, discussions should happen early to allow individuals time to consider the options, ask questions, and to plan accordingly.***
9. ***Patients and their families should be provided with standardized information resources, such as online material or pamphlets to help guide responses to donation inquiries. The decision to proceed with MAID or WLSM must precede discussions about donation.***

Recommendations: Consent

10. ***The patient must have the ability to provide first-person consent to MAID or WLSM as well as to organ and or tissue donation.***
11. ***Physicians, MAID assessors, and WLSM or MAID providers should be cognizant of the risk of coercion or undue influence on patients to donate their organs; however, the patient's altruistic intentions should not be discouraged.***
12. ***Donation discussions must respect patient autonomy and first-person consent should be obtained and upheld. Although it is welcomed and encouraged that family members are included in donation conversations, consent must be obtained from the patient and conversations should be focused on them.***
13. ***The individual should be informed and understand that they may withdraw consent for MAID or donation at any time, and that withdrawal of consent for donation does not affect their consent for, or access to, MAID or WLSM.***

14. ***The donation team should make every effort to resolve conflict, through dialogue, between the patient's expressed wishes to donate and a family's disagreement. First-person consent should direct all subsequent decisions unless consent was revoked.***
15. ***If a conscious and competent patient provides first-person consent to donate after WLSM but subsequently loses decisional capacity, there is a strong case for proceeding with donation after WLSM because the patient was adequately informed about the decision by a trained donation expert and gave consent in the context of their illness and an anticipated imminent death. However, if a patient loses capacity prior to the MAID procedure, then MAID procedures cannot be carried out.***
16. ***The donation team must understand and abide by the laws and policies of their jurisdiction with respect to reporting of MAID deaths (e.g. coroner, special committee). To facilitate donation, these parties should be contacted prior to the MAID procedure, in accordance with the current laws and policies.***

Considerations:

- The conversation should be framed as an approach rather than a request; information should be offered in an unbiased way that allows the patient to make an informed decision consistent with their preferences, values, and beliefs.
- The patient's vulnerability to influence MAID/WLSM and donation may be increased if they have a personal association with a transplant recipient, an individual on a transplant waitlist, or a previous living or deceased donor.
- In accordance with privacy laws, consulting an organ donor registry to discern a patient's willingness to donate may help guide the decision whether or not to make an approach. However, it should be noted that while public opinion polls in Canada show that over 90 per cent of people support donation[39], only approximately 30 per cent have registered an intent to donate. Therefore, failing to approach patients on the basis that they have not registered may deny the opportunity to many who are supportive of donation.
- If a patient who has indicated a desire for WLSM inquires about MAID with the intent of improving their opportunity to donate, treating physicians may request advice from the ODO/donation program and the hospital bioethicist on this topic; however, the donation team should not engage with the patient or families until the EOL plan is decided upon. In this regard, the decision to end one's life or allow a natural death should not be driven by the desire to donate organs, but it may be acceptable for the specific end-of-life decision (e.g. MAID rather than WLSM) to be informed by the patient's separate wish to donate. One workshop participant stated that, "we have a duty to respond to questions asked of us by patients [and] it is our duty to bring up the options for dying."
- The clinical team should establish the patient's preferences regarding the confidentiality of their EOL decision and whether they want family members or friends to participate in these discussions. Care should be taken to ensure the patient's choice to pursue MAID/WLSM is not breached to people the patient does not want to disclose this information to during donation conversations. For instance, if the donation coordinator

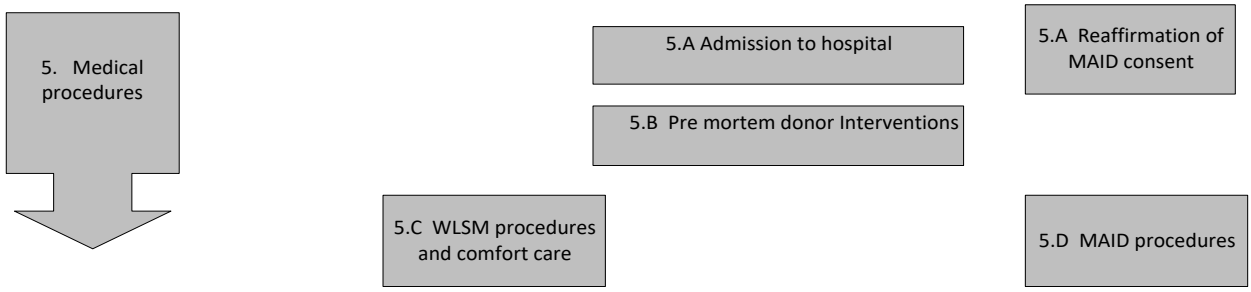
plans to make an approach at an ALS clinic, ensure that the patient gives prior consent to having any family members or friends in attendance during these discussions

- Considerations should be given for different modalities to communicate with patients. Some patients may have difficulty communicating by telephone. If in-person conversations are impractical, consider video chat technology as an alternative as well as the use of visual aids and linguistic interpretation and translation services.
- All communication must be per provincial privacy legislation, local policy and procedure and in accordance with any guidelines for electronic communication.

Recommendations: Donor testing and evaluation

17. ***Primary care physicians, and staff or organ donation organizations, MAID providers and transplant teams should work to minimize the impact and inconvenience to the patient of donating their organs. This could include scheduling home visits for blood draws and coordinating investigations (e.g. x-rays, ultrasound) to minimize hospital visits and inconvenience to the individual.***
18. ***Transplant teams and surgeons should work with the donation team to determine the minimum necessary investigations, to avoid the burden of excessive assessments and testing.***
19. ***Donor teams should routinely discuss the potential impact of unanticipated results from the donor investigations, including previously undiagnosed infectious diseases, and their impact on public health reporting and contact tracing.***

5. Medical Procedures



5.A) Reaffirmation of consent

- Consent is a process – it is an ongoing discussion, not an event
- For MAID, the patient must reaffirm their consent prior to the MAID procedure
    - Patient must maintain capacity to provide consent
- If donation is requested, consent should be confirmed prior to administration of antemortem interventions, such as heparin

5.B) Antemortem interventions

- The EOL care team may administer heparin, steroids, etc. as requested by the transplant team upon prior consent of the patient

- Arterial line (for death determination) may be inserted, upon prior consent of the patient

5.C) WLSM Procedures

- Procedures occur in accordance with provincial and organizational policies and procedures, and consistent with principles of palliative comfort care during WLSM
- May occur in the Intensive Care Unit (ICU) or operating room, depending on optimal logistics

5.D) MAID procedures

- For deceased donation to occur, MAID must take place in a hospital
- After reaffirmation of consent, a medical practitioner or nurse practitioner may:
    - Administer a substance to a person, at their request, that causes their death; or
    - Prescribe or provide a substance to a person, at their request, so that they may self-administer the substance and in doing so cause their own death

Note — For organ donation to be considered after MAID, the substance must be administered by a medical or nurse practitioner.

Stakeholders in this phase of care

- Patient and family (with patient's consent)
- Primary treating team
- MAID providers
- ODO personnel, surgical retrieval team

<u>Recommendations: MAID procedures</u>

20. ***Consent for MAID must be reaffirmed prior to the MAID procedure. The health care team or MAID provider should reaffirm consent prior to relocation to the hospital and prior to beginning any antemortem interventions for the purposes of facilitating donation. This may reduce the momentum of the donation process and reduce the potential for patients to feel pressured to continue with MAID in the interest of ensuring organ donation.***

Considerations:

- There may be a greater need for cooperation among health care professionals and institutions responsible for EOL care, surgical retrieval of organs, and transplantation, as well as the coroner, in the days leading up to the patient's death.[16, 20] This is particularly important when there may be a prolonged period between the patient's decision to pursue MAID/WLSM and donate their organs, and the date of their MAID/WLSM procedure.
- To preserve the opportunity to donate, the patient must choose a time and location for their MAID/WLSM that permits surgical retrieval of organs. This will require planning and it may put the patient at a disadvantage to wait until final approval for MAID to

discuss donation. However, some participants felt that there was a risk of conflating the two decisions if donation is raised prior to approval for MAID.

- Changes to established plans related to the patient's EOL care, such as a change of date or location of their MAID procedure to preserve the opportunity for donation may be distressing to the patient and their family and should be avoided if possible. If changes are required, the patient should be reminded that they may withdraw consent to donate so they may proceed with their MAID procedure as planned.
- Once consent for donation is given, the patient's willingness to withdraw consent may be challenged by the momentum of the donation process. To mitigate pressure on the patient to proceed with their MAID procedure followed by donation of their organs, consider:
    - performing the MAID/WLSM procedure in a separate location from where surgical retrieval of organs would occur; and
    - avoiding any contact between the patient and the recovery/transplant team.
- Loss of capacity need not preclude deceased donation after WLSM if the circumstances of the patient's death are compatible with recovery and transplant. Loss of capacity in MAID candidates precludes the MAID procedures and thus deceased donation will not proceed.
- While there was no consensus among the participants, if the donation team believes that the family is failing to respect the patient's wishes, there might be grounds to challenge a family veto in the event of incapacity and proceed with surgical retrieval of organs following after WLSM.
- Overriding a family's decision to not proceed with donation may have implications for public attitudes toward the donation process. Negative public sentiment could vilify the ODO for proceeding without the family's consent. Conversely, the public could celebrate the ODO for actualizing a patient's dying request despite opposition. While public trust in the organ donation processes is critical, public perception should not guide in the circumstances of managing a family veto.
- The risk of negative public perception could be mitigated by emphasizing the first-person consent in these cases[24], by adopting transparent, consistent processes[15, 18], and by separating the decision for WLSM from discussions about donation[14]. However, this must be balanced against the perceived and real risk of coercion of the patient to donate.

WLSM and MAID procedures are generally scheduled well in advance and take place during weekdays within regular daytime hours. If the patient requests donation, the EOL process will occur in a hospital where organ recovery occurs, which typically means a larger centre. This should allow for advanced planning to ensure the availability of staff willing to participate in donation after MAID. Hospitals may wish to keep lists of those willing to participate in both MAID and organ donation after MAID to provide this care when it is requested.

6. Death determination and surgical retrieval of organs

All deceased donation cases must adhere to the Dead Donor Rule which means:

i) The removal of organs must not cause the patient's death.
ii) The donor must be declared dead by either circulatory or neurological criteria before organs are retrieved.

6.A) Circulatory arrest and death determination

- The patient is determined dead according to circulatory criteria based on the permanent cessation of antegrade blood flow with a five-minute observation period
- Cessation of antegrade blood flow is most reliably confirmed by the absence of pulsatile blood pressure with intra-arterial monitoring.
    - While arterial line monitoring is recommended, the patient is not required to consent to arterial line insertion
    - In the absence of arterial line consent, alternatives to confirm the absence of circulation may include the absence of a palpable pulse combined with one or more of:
        - carotid arterial perfusion ultrasound
        - aortic valve ultrasound
        - asystole by EKG monitoring
- Five-minute 'no-touch' period continuous observation to rule out autoresuscitation
- Circulatory-determined death must be confirmed by a second physician
- Separation of teams: Transplant and surgical retrieval team cannot be involved until death is declared

6. B) Organ and tissue recovery
The deceased donor is transferred to the operating theatre for surgical recovery of organs

Stakeholders in this phase of clinical pathway

- Patient and family
- Primary treating team and/or EOL care team
- Physician for first death declaration
- Physician for second death declaration
- ODO personnel, surgical retrieval team

Recommendations: Determination of death

21. ***The dead donor rule must always be respected. Vital organs can only be procured only from a donor who is already deceased; the act of procurement cannot be the immediate cause of death.***
22. ***For determination of death, absence of a palpable pulse alone, is not sufficient. If arterial monitoring is not available, alternate means of determining absence of anterograde circulation should be used in conjunction with absence of a palpable pulse, such as a carotid perfusion ultrasound, Doppler monitoring, aortic valve ultrasound or an isoelectric EKG to determine asystole.***
23. ***As with all cases of DCDD, death should be confirmed by a second physician after a 5-minute 'no touch' period of continuous observation during which time no donor-based interventions are permitted.***

Considerations

- There was no consensus on the requirement for arterial monitoring for donation after MAID. Some argued it was unnecessary while others advocated for the importance of an arterial line and suggested seeking consent from the patient for one on the basis that it would improve the reliability of death determination.
- There was some debate concerning whether a 'no touch' period, which is current practice for DCDD cases, is necessary after MAID given the patient's wish to die.[16, 17] However, the workshop participants did not advocate for abandoning the 'no touch' period and, in accordance with the dead donor rule, felt that it should remain current practice for DCDD cases, including those after MAID or WLSM.

Recommendations: Protection for patients

Separation of decisions

24. ***To avoid any real or perceived conflict of commitment, health care practitioners should separate the decision regarding WLSM or MAID from discussions concerning donation. Providers who are assessing eligibility for MAID should not be involved in donation discussions. Discussions concerning donation should happen only after WLSM decisions are made, or patients have been found eligible for MAID by 2 independent assessments.***
25. ***The primary health care team should acknowledge patient inquiries concerning donation that are made prior to a decision to proceed with MAID or WLSM. General information on deceased organ and tissue donation may be provided. However, specific discussion and decisions pertaining to donation should wait until the decision to proceed with MAID or WLSM has been finalized.***
26. ***Patients may wish to postpone their MAID procedure, owing to a temporary improvement in their health or an event they wish to experience prior to their death. The freedom of the patient to postpone their MAID procedure must be reinforced and preserved and every effort should be made to honor their wishes to donate their organs should their MAID procedure be rescheduled.***

Directed and conditional donation

27. ***No restrictions should be placed on potential organ recipients. Directed deceased donation (direction of a patient's organs to a specific recipient) or conditional donation (e.g. organs will be donated only if the patient can place conditions on what social groups may or may not access them) from patients considering MAID or WLSM should be neither offered nor encouraged.***
28. ***Living donation prior to death from patients considering MAID or WLSM should be neither offered nor encouraged.***
29. ***Should a patient insist on directed deceased donation or living donation prior to death, the request should be considered on a case-by-case basis.***

Considerations:

- Most forum participants expressed a great deal of discomfort with directed deceased donation and some felt that it should not be an option for MAID patients. There was greater discomfort with the risk of pushing terminally ill patients to seek living donation prior to their death to direct their donation.

Separation of roles

30. ***Consistent with current guidelines and practice regarding DCDD, separation should be maintained between the EOL care, donation, and transplant teams. Surgical recovery and transplant teams should not be involved in the patient's end-of-life care or MAID or WLSM procedure. The only exception is insofar as they may provide guidance for minimal requirements for donor investigations or premortem interventions.***
31. ***Patients who wish to donate their organs after MAID or WLSM, but who request that their decision to pursue MAID/WLSM remain confidential, should be informed of the risk that their family members may discover incisions associated with surgical retrieval of organs. They should be encouraged to disclose their decision to family members; however, there is no obligation to stop the donation process should the patient wish to maintain the confidentiality of their MAID or WLSM procedure.***
32. ***That an organ donor received MAID should not be disclosed to the potential recipient during allocation; however, medically relevant information regarding their underlying disease may be disclosed according to guidelines for exceptional distribution, where applicable.***

Considerations:

- In practice, health care teams will require alignment and coordination along the way to facilitate the opportunity to donate for a patient who has requested MAID. In some cases, the patient's treating physician, who would have a role in advocating for the patient's wish to donate, may also serve as a MAID assessor or provider.

- Given the patient's capacity to drive the process and the potential that they may want to speak to the donation team directly, strict separation between the treating physician, MAID provider, and donation team may not be feasible nor necessary.
- Having the patient disclose the MAID/WLSM or donation decision to family members, mitigates the risk that families will inadvertently discover the patient's choice and the potential for compromised trust.
- Potential donors should be informed about their province's rules regarding the documented cause of death listed on the death certificate, since this is a document that family members may see at some point.

Recommendations: Supports for patients and families

33. ***Specially trained professionals, such as donation physicians and coordinators, patient navigators, or social workers, must be available to answer the patient's questions and facilitate the coordination of their MAID or WLSM and donation. This may take place over a period of many weeks. The patient and their family must be provided with specific instructions on how to access these resources.***
34. ***Support should be available in an optimally convenient location and setting for the patient, such as home visits or coordination with visits to clinics. For patients in remote locations, video-based technologies may be of assistance.***
35. ***The donation team should work with the patient, their family, and the MAID or WLSM provider to develop a plan and best possible options for the MAID or WLSM procedure that accommodates the wishes of the patient, preserving the opportunity to donate and reconciling coordination of hospital logistics.***
36. ***Ongoing access to support for patients and their families is critical. Despite patient consent, donation might not proceed due to failure to find a suitable recipient, deterioration of health that compromises medical eligibility to donate, surgical findings during organ recovery, or withdrawal of consent by the patient. These patients and their families must continue to receive support even if donation does not proceed.***
37. ***Continued support must be available to family members after the patient's death. Processes need to be developed to ensure families are given the opportunity to provide feedback on their experience, which may help with their grieving process and may help inform quality improvement measures.***

Considerations

- Proper briefing of families, so that they know what to expect from the MAID and donation procedures, may assist family members and friends to cope with the process and prevent additional stress due to lack of information or misunderstanding.
- After the death of the patient, families must continue to receive support including information about available resources. At the same time, they may be asked to provide input about their experience with the process to benefit future patients and families. It may also be useful to conduct additional follow up with families 6-12 months after the patient's death to allow some time for reflection and to cope with the loss.

Recommendations: Amyotrophic lateral sclerosis (ALS) and neurodegenerative diseases

38. ***People with ALS and patients with other non-transmissible neurodegenerative diseases should be offered the opportunity to donate organs after their death.***
39. ***ODOs should exercise caution regarding allocation of organs from donors with undiagnosed or rapidly progressive neurodegenerative diseases, as these may pose elevated risks to recipients. Organ allocation in this context should follow existing exceptional distribution policies and practices.***
40. ***Transplant professionals must balance the benefits of the transplant against any potential for harm of receiving a transplant of an organ from a donor with a neurological illness. Transplant professionals must use their discretion to help the transplant candidate navigate the decision. The surgeon may wish to consult the donor's neurologist to help inform their advice to the transplant candidate.***
41. ***All cases of ALS or other neurodegenerative diseases that arise in transplant recipients should be reported to Health Canada to determine potential associations with donor illness and baseline risk of neurodegenerative illness in transplant recipients (e.g. whether transplant recipients, in general, have rates of ALS that differ from the general population).***
42. ***Physicians who follow organ recipients should be: aware that the donation was by a patient with neurodegenerative disease such as ALS, aware of theoretical transmission risk of neurodegenerative diseases, and cognizant of symptoms or complaints that warrant further investigation by a neurologist to determine if a neurodegenerative disease is present.***
43. ***Active monitoring (i.e., regular visits to a neurologist) is NOT recommended for transplant recipients who have received an organ from a donor with a neurodegenerative disease. Neurological monitoring would impose a substantial burden on the recipient and present no benefit to the recipient, particularly as there is currently no value in early detection of these illnesses.***
44. ***Information resources should be available for transplant candidates and for transplant professionals to help with the decision regarding whether to accept or refuse an organ for transplant. A means of obtaining a consult from a specialist neurologist in neurodegeneration may also be useful in helping the potential recipient make an informed decision. This information should also be available to ODOs and the donation professionals responsible for assessing the eligibility of the patient who is considering donation.***

Considerations:

- Consider giving recipients the opportunity to accept or refuse organs from patients with neurodegenerative diseases. This may be particularly important for transplant candidates with a family history of ALS or for young transplant candidates who would have a long post-transplant life expectancy.
- The transplant team should take care to help the patient understand the estimated risk of accepting an organ from an ALS donor in comparison to other risks of transplantation as well as the risks associated with progression of organ failure upon refusing the organ

to wait for another to become available. Some forum participants worried that the harm of disclosing a neurodegenerative disease, and loss of donor confidentiality, would exceed the risk of disease transmission.

- Transplant surgeons may perceive a medico-legal risk associated with transplanting an organ from a donor with a neurodegenerative illness. The recommendations and considerations arising from this report should be disseminated to surgeons.
- It is unknown whether transplant recipients may have an elevated risk of developing neurodegenerative diseases compared to the general population due to their underlying illness, the transplant drug regimen, or some other characteristic. Therefore, it is important that all cases of neurodegenerative illness in recipients, whether they received an organ from a donor with a known illness or not, should be reported so that the baseline risk of neurological disease can be determined for this population, unrelated to having received an organ from an ALS donor.
- Organs from donors considered to be of higher risk of transmitting illness to a recipient may be more appropriate to allocate as an immediate life-saving intervention for transplant candidates who would die otherwise, or patients whose post-transplant life expectancy is relatively short. Extra caution should be encouraged for young patients and for those for whom the transplant would be life-enhancing rather than life-saving.
- Transplant candidates have very little time to decide whether to accept an organ that is offered to them. To help weigh the risks and benefits, information should be provided to those on the waitlist to better equip them to make this decision. A short pamphlet for transplant candidates on the risks of transmission of neurological illness, as well as ongoing dialogue with their transplant coordinator, may be useful to this end.
- Compared to other DCDD cases, donation by conscious competent patients may offer more time to plan the organ allocation to a waitlisted transplant candidate – there may be opportunities to tailor current allocation processes. Current transplant candidates could be consulted for input into the development of these processes.

Recommendations*: Health care professionals*

45. ***Health care professionals may exercise a conscientious objection to MAID or WLSM specifically, but they should strive to accommodate the wishes of the donor by ensuring that their objection to MAID or WLSM does not impede the ability of the patient to donate.***
46. ***Health care professionals should act in accordance with provincial and territorial requirements as well as professional and regulatory college requirements for effective referral.***
47. ***Health care professionals responsible for the care of conscious, competent patients who have requested WLSM or MAID and donation should be briefed so they are familiar with the patient's end-of-life plan and relevant policies and procedures.***
48. ***Debriefing after the procedure (i.e., MAID or WLSM with or without donation) should be offered every time to all members of the health care team who participated. Debriefing by an external resource may be beneficial so that team members feel comfortable sharing their experience.***

49. ***Psychological support, such as that offered through employee assistance plans (EAP), should be accessed when required. Staff of employee assistance plans may benefit from additional training and education regarding MAID with or without donation to adequately meet the needs of these health care professionals.***
50. ***Hospitals must ensure that staff are available who are willing and able to honor the patient's wishes to donate after their death or have an effective referral plan in place.***
51. ***Participation of health care professionals in MAID and in organ donation by patients who received MAID should be voluntary, when possible, without interfering with the patient's access to care. The health care team should be well informed and well briefed so that they understand the patient's wishes and the outcome they are working towards as well as relevant policies and procedures.***

Considerations

- There is some disagreement in the literature concerning the limits of conscientious objection to donation after MAID. However, in practice, whether objections can be substantiated on grounds of conscience may be less relevant because ODOs can draw from a large pool of professionals to build their procurement teams and they will typically have many days' notice for a case of donation after MAID. Every effort should be made to ensure that participation by health care professionals is voluntary. See Section F of this document - System Oversight, Accountability, and Quality Assurance.

<u>Recommendations: Reporting</u>

52. ***Clinicians must be aware of the reporting and documentation requirements for MAID and WLSM and for donation in their jurisdiction.***
53. ***Records pertaining to organ donation after MAID, as well as donation and transplant outcomes, should be reported federally and be accessible to clinicians, researchers, and administrators. Transplant outcomes should be easily cross-referenced with the underlying illness of the MAID donor.***

Considerations

- There were also calls for oversight of the process by an external body, such as a coroner.[20, 27]
- Because donation, in general, and donation after MAID, in particular, is such a rare event, care should be taken when reporting statistics publicly to avoid inadvertent breaches of confidentiality (i.e. identifying donors to recipients or identifying donors as having received MAID). Tools are available to help determine how often, and for how large a population, data may be released.
- Data should be used for quality assurance and improvement in the process of organ donation after MAID. Aspects of the donation sequence that should be assessed and/or monitored include, but are not restricted to:
    - Patient experience prior to death;

- Family experience (useful as therapeutic alliance for organ donation after MAID is with patient);
- Quality of the donation conversation (setting, timing, expertise of health care professional);
- Adherence to policies and protocol, separation of roles;
- Missed referral opportunities;
- Time from MAID administration or death determination to surgical recovery of organs;
- Warm ischemic time; and
- Health care professional experience; pre-brief, debrief, access to support.

Background

MAID and WLSM are pathways by which conscious competent patients may choose to hasten their deaths. While there may be differences in the characteristics of conscious competent patients who undergo MAID or WLSM, in both scenarios, the patient has a life-limiting illness with poor prognosis and has the capacity to provide first-person consent.

1. The conscious competent patient

Conscious competent patients differ in several ways from critically ill, unconscious patients, including the following possible situations:

a) May reside at home or in a long-term care or assisted-living facility, so are less available for hospital-based testing and assessment;
b) May wish to choose the time and circumstances of their death via MAID or WLSM;
c) May have specific plans for how they wish to spend the final period of their lives (i.e. visiting friends and family, travelling);
d) May experience pain, discomfort, or inconvenience associated with assessing their eligibility to donate organs, such as blood and imaging tests;
e) Are more sensitive to the burden of any additional steps or stress required for donation as part of their EOL care process.

One example of an illness for which a patient may choose either MAID or WLSM is amyotrophic lateral sclerosis (ALS). In general, patients with ALS may die from respiratory failure secondary to progressive deterioration of neuromuscular function.

As ALS cases present many challenging and complex issues for discussion, deceased donation by ALS patients is covered separately in Appendix 6. Patients seeking WLSM or MAID for multiple sclerosis, chronic obstructive pulmonary disease, and end-stage heart failure may also be eligible to donate their organs after death.

2. The decision for WLSM or MAID and eligibility

2.A) Consideration of end-of-life care

When a patient is dependent on life-sustaining medical interventions or is suffering from illness that meets the criteria set out in the MAID legislation[4], any decision regarding their EOL care must follow careful discussion and consideration of all their options with their treating physician.

If a patient wishes to seek MAID or WLSM, they may request this as an EOL care option from their family physician, specialist physicians, or other health care professional. Their physician may agree to perform the MAID or WLSM procedure for their patient or they may refer them to another physician. In the case of MAID, this physician may be referred to as the MAID provider.

2.B) Consensual decision for WLSM

A patient who is requesting WLSM will discuss the reasons for the request with their attending physician. The patient needs to be competent to consent to WLSM but there is no legally mandated process for determining WLSM eligibility, nor is there a required waiting period. Any legally competent adult can refuse medical care, including life-sustaining therapy and ask the removal of therapies that have previously been started (e.g. discontinuing mechanical ventilation). However, there should be consensual agreement between the patient and their treating physician on the decision to WLSM.

2.C) Request for MAID

MAID is administered under the legal framework of Bill C-14 (and Quebec's Bill 52) and eligibility for MAID is limited to those who have a 'grievous and irremediable medical condition' as defined in the bill.[4, 5] To seek approval for MAID, the patient must make a written request that is signed, dated, and witnessed. For those unable to write, another adult can sign the request under the requestor's clear direction. The request for MAID is reviewed by two independent assessors (the first assessment and the second assessment) to determine if the patient meets the criteria for MAID and whether their consent was given voluntarily and free from external pressure. For MAID (but not WLSM), there is a legally mandated reflection period of ten days between the request and the MAID procedure. This reflection period may be reduced if there is expected loss of capacity or death is deemed imminent.

2. D) MAID eligibility and approval

The wording of current legislation around eligibility for MAID is subject to interpretation, allowing medical professionals to apply judgment on a case-by-case basis but creating some confusion concerning the limits of eligibility. This particularly applies to the language specifying that the patient must have a "grievous and irremediable" illness and that "natural death has become reasonably foreseeable".[3,4,5] Furthermore, it is difficult to define at what point suffering becomes intolerable, particularly if a patient doesn't want to proceed with MAID immediately after they are determined to be eligible.

There are several factors that may compromise a patient's ability to give free, informed consent for MAID, such as a primary mental illness or loss of capacity. There are three specific situations that are currently ineligible for MAID but that are being studied by the federal government for potential future eligibility: (1) MAID for primary mental illness; (2) advance medical directives for MAID for patients who may lose capacity in the future as a result of their illness; and (3) mature minors.

In assessing a patient's eligibility, MAID is balanced against alternative EOL care options, such as palliative care and palliative sedation; however, it is important to note that patients who request MAID may not be eligible for palliative sedation and palliative care may not be effective at relieving suffering for some patients approaching end-of-life.[3,4]

3. Referral and suitability

3.A) Referral to the ODO

Conventional DCDD after WLSM requires referral of patients to the ODO at an early time point prior to initiation of WLSM procedures.[35] This is to allow the ODO to assess the patient for medical suitability for deceased donation and to approach the family in order to request consent for donation. The same applies to conscious competent patients: early referral helps preserve their opportunity to donate their organs after death. However, the timing of the referral must not interfere with the patient's EOL decision — assessment of the patient's medical suitability for deceased donation prior to a decision for WLSM or approval for MAID may be perceived as a conflict of interest.

The provinces of British Columbia, Manitoba, Ontario, Quebec have mandatory referral laws — the ODO must be notified when death is imminent or established. Similar legislation is awaiting proclamation in Nova Scotia, while Alberta has mandatory consideration after death determination. At the time of this report, Saskatchewan legislation has made it permissive to share personal information of a person whose death is imminent with the ODO for the purposes of determining suitability to donate, but a referral is not mandatory. New Brunswick, Prince Edward Island, and Newfoundland and Labrador do not have legislation in this regard. In Ontario, a TGLN guidance document notes that "notification does not imply medical assistance in dying will proceed or that an approach will occur".[36] Instead, the best way forward would be determined jointly between the ODO and the most responsible physician. Thus, referral to the ODO does not automatically trigger an approach or request for consent to donate but instead allows donation conversations to be directed to patients that may have the potential to donate.

3.B) Confirm eligibility for organ and tissue donation

Most patients that request MAID will not be eligible to become deceased organ donors due to their underlying illness, such as metastatic cancer or rapidly progressing neurological illness, their age, or other contra-indicating factors. The initial evaluation is not sufficient to ensure that the patient's organs are suitable for donation; however, it allows for early identification of those that will not be eligible to donate and avoids dedication of resources and the stress on patients and health care professionals of discussing donation in cases where it is not a realistic outcome. In addition, the logistics of deceased donation in the conscious competent patient are complex and may pose obstacles to offering donation depending on geographic location.

4. Approach and consent

4.A) Information about organ and tissue donation shared with the patient

Conversations on the topic of deceased donation are inherently difficult. Leading practices have been developed in Canada for providing individuals and their SDM with the best opportunity to make an informed decision.[37] These leading practices were developed to guide EOL care and donation discussions with the SDM of unconscious patients after devastating brain injury. While these leading practices may be helpful in guiding an approach for the conscious competent patient, there may be differences with respect to the timing and setting of the conversation,

the language used, the skill set and the requirement for ongoing follow up. Furthermore, there may be increased discomfort and emotional difficulty among health care professionals in conducting these conversations in the first person with a patient, rather than with a SDM.

Routine request for organ and tissue donation

While several countries have adopted a model of opt-out (presumed) consent to donate, in Canada, deceased donation is dependent on provision of consent by patients or their SDM.[14, 30-32] Donation after WLSM or MAID allows for first-person consent by a conscious competent patient rather than requiring a substitute decision maker to speak on behalf of the patient; however, there are still ethical questions surrounding the consent process. Arguments for and against routine requests are summarized in Table 4.

There have been calls to routinely offer deceased organ donation as part of the MAID/WLSM EOL pathway[16, 17]; however, at present, there is variability, both within Canada and internationally, concerning whether donation is discussed with conscious competent patients routinely or only when patient-initiated.

The literature is divided concerning whether patients requesting MAID or WLSM should be routinely approached or whether donation should be considered only upon a spontaneous request by the patient. The argument in favour of routine requesting is supported by the principles of autonomy and justice, whereby all patients are given the opportunity to make an informed choice.[14, 23, 38] Conversely, some authors argue that patients may be influenced or coerced to consent to donating their organs[14, 16, 25, 27] and it may be that the very act of offering the opportunity puts pressure on the patient.[14, 24, 38]

Some authors caution that patients may choose to die in order to donate their organs to save the lives of others[16, 17, 27, 28] or may choose to end their lives earlier than they would otherwise, in order to donate.[17] That said, the Dutch practice manual states that donation should not be discouraged or disallowed solely because a patient expresses altruistic motivation.[27]

Table 4. Workshop discussion outcomes for and against routine request

FOR routine request

• Health care professionals should avoid deciding for the patient or assuming to know their values
• They should not assume patients and their families know about the possibility of donation; they may support donation but assume they are ineligible
• They have a moral/ethical duty to inform patients of their EOL options, including donation
• There may be legal requirement to refer to ODO in case of 'imminent death' (varies province by province)
• Donation may give meaning to the patient's death
  ○ May provide comfort to patient prior to their death
  ○ May assist family in grieving

AGAINST routine request
• There is risk of pressuring or influencing the patient

    - May feel they have to consent to donate to access MAID/WLSM
- If patient consents, but is then deemed ineligible or if their organs are not allocated, they may feel regret or loss during their final days of life
- Routine requesting in this setting may erode public and professional trust in the donation and/or EOL care system

Who needs to be prepared for a donation conversation?

In jurisdictions that do not routinely approach, or if a conscious competent patient asks about donation before an approach from a donation coordinator has occurred, requests about donation are likely to be directed to the patient's treating physician, MAID provider, or other member of the EOL care team. Health care professionals must be prepared, educated and equipped, and have access to necessary consultation, to appropriately address these questions.

Stakeholders in Canada have invested in education around deceased organ donation for critical care and emergency department staff, where potential donors have typically been identified. However, the care team for patients seeking MAID may not have been targeted for extensive education and, in the case of MAID providers, have no unifying professional association through which education programs could be conveniently delivered.

Family doctors, neurologists, and MAID providers involved in the EOL care of conscious competent patients outside of critical care environments have less experience with organ donation, potentially presenting a barrier to access to donation information and services for patients.

The timing of donation conversations

There is consensus among ethicists and EOL care medical practitioners that the decision to die by MAID or WLSM must be separate from, and must precede, the decision to donate. [17, 23, 24, 38] The rationale for separation is that discussions concerning donation may provide external influence or pressure on the individual to proceed with MAID/WLSM.

However, leaving the donation conversation too late in the EOL care process may place the individual at a disadvantage. Donation has influence on the EOL care process, such as the requirement for death to occur in hospital instead of at home and may place additional burden on them insofar as they must undergo donor assessments and antemortem interventions. It is important for the individual to be aware of how these requirements may alter EOL care plans.

While it was agreed that the donation conversation must take place after the decision for MAID, there was no consensus on the appropriate timing of the conversation with respect to the approval for MAID. Some participants felt that an opportune time to approach the patient might be immediately after the first MAID assessment. This would ensure that the patient's decision concerning MAID has already been made but would still allow time to plan the MAID procedure to accommodate donation.

The setting of donation conversations

The setting of the conversation should be patient-centered, and consider:

a) The patient's ability to travel;
b) Potential difficulty for the patient to communicate by telephone or videoconference;
c) The patient's priorities with respect to how they spend their time during their final days of life; and
d) The confidentiality of the patient's choice to pursue MAID or WLSM that may include privacy from family members and their community.

For some patients, the ideal setting may be their home. In this way, an additional trip to a clinic or hospital should be avoided. If this is not possible, the conversation could be scheduled to coincide with a clinic or hospital visit.

Language

Some health care professionals, even those well-versed in deceased donation discussions may have little experience speaking to the potential donor, themselves, rather than their family or SDM. One patient contributor reported that the coordinator addressed the patient's spouse, rather than the patient directly. There were also objections raised by patients to the language used, preferring 'your body' and 'your organs' rather than 'the body' and 'the organs'. The phrase 'harvesting organs' was also perceived as offensive and those interviewed recommended using 'retrieving' or 'recovering' instead.

Implications of donation on end-of-life care

It is important during the patient's decision process that they understand that donation will have implications for their EOL care. In Canada, the vast majority of deceased donation conversations occur with the families of hospitalized patients who have suffered a devastating brain injury are unconscious and dependent on life-sustaining technologies in the ICU.

By contrast, conscious competent patients differ in important ways as discussed in Section 1, which may present potential barriers to donation. Indeed, the literature review (see References) and the patient contributors to the workshop identified frustration with changes, compromises, and additional steps required to allow them to become donors but have no direct benefit to them. These include:

a) Completion of a social/medical questionnaire, which covers topics such as sexual history, alcohol and drug use, and other risk factors for infectious diseases, is standard for all potential donors; conscious patients may find it to be extremely personal and uncomfortable;
b) The requirement to die in an acute care hospital, as opposed to at home or at a long-term care, residential, or assisted-living facility[14, 16, 20, 27, 38];
c) Hospital/clinic visits prior to MAID to assess eligibility to donate and organ quality (e.g. blood work, imaging)[20, 27];
d) Antemortem interventions to facilitate death determination, such as an arterial line, which may be uncomfortable or painful;

e) Antemortem interventions, such as the administration of heparin, to maintain/improve organ quality[14, 27];
f) Request to change the day or time of their death to accommodate access to the acute care hospital for EOL care, surgical retrieval and allocation logistics;
g) Location of death and requirement for transfer to the operating room immediately after death for surgical retrieval of organs, which may prevent or delay the family from having a quiet time to say goodbye or grieve with the body of their loved one.[14, 27, 38]

Patients must weigh these additional steps while managing their illness and coping with the realities of their own prognosis. Based on their own comfort and preferences over how they wish to spend their last days, they may have questions and decline some investigations or donation interventions.

4.B) First-person consent for organ and tissue donation

During donation conversations, the health care professional making the approach or request must provide enough information about the donation process and the implications on the patient's EOL care that the patient is able to provide informed consent. Consent for ante-mortem interventions to facilitate surgical retrieval of organs and transplantation should also be requested at this time. Similar to consent for MAID or WLSM, this consent may be withdrawn at any time should the patient change their mind.

Family veto

If a patient loses capacity after consenting to donation, it is possible the family may intervene and override the decision to donate. With respect to conventional deceased donation, in which the patient is not able to speak for themselves, family members' objections to a loved one's prior intent to donate their organs, such as via an organ donor registry, may prevail. This is, in part, because the patient's previously stated intent may not have been adequately informed and lacked context. There is interprovincial variability with respect to the law concerning disagreements between an incompetent patient's previously stated wishes and those of the family.

Since, currently, consent for MAID must be reconfirmed immediately prior to the MAID procedure, this type of conflict cannot occur. However, in cases when a patient has consented to WLSM and then lost capacity, or should the legislation change to allow advanced, binding, consent for MAID even if capacity is lost, this may become an issue in the future.

4.C) Notification of the coroner/medical examiner of a MAID death

In some provinces, the coroner may have to grant permission prior to surgical retrieval of organs from a patient that has died by MAID; in such cases, it is important that the coroner be notified in advance of the death so that such permission may be obtained.

4.D) Donor testing and evaluation

Typical DCDD donors are critically ill, unconscious, and hospitalized; however, conscious competent donors may be living at home or outside of an acute care facility. Further, having decided to end their life at a predetermined date, they may place a high priority on how they

spend the final days of their life. This creates challenges for assessing patients for their eligibility to donate since access to the patient for imaging, blood work, and other tests will require coordination with the patient, their family, donation personnel and other health care professionals. Care should be taken to minimize the inconvenience and burden on the patient required to complete the organ testing and evaluation required for donation. In some cases, donors may opt to donate fewer organs in order to limit the burden of testing.

5. Medical procedures

5.A) Admission to hospital and reaffirmation of consent

For organ donation to proceed, patients must be admitted to hospital prior to WLSM or the MAID procedure. Admission to hospital may be a significant event for patients receiving MAID as they move from the comfort of their home and familiar surroundings; however, it is necessary for organ donation to occur.

Immediately prior to the EOL care team administering the MAID medications, it is legally required that the patient reaffirm consent for MAID. This is to ensure they have the opportunity to change their mind or withdraw consent prior to their death. However, this requirement also means that patients who lose capacity, through progression of their illness, through sedation, or another factor such as stroke, cannot proceed with MAID.

By contrast, there is no requirement to reaffirm consent for WLSM and the EOL care team of those who have given consent and, thereafter, lost capacity may still proceed with WLSM.

Should a patient lose capacity/competence after the initial MAID decision, they would no longer be eligible for MAID and thus would not proceed to donate. However, WLSM and donation could still proceed, even if the patient lost capacity to reaffirm consent, on the basis of their prior expressed decisions.

5.B) Antemortem interventions

Prior to administration of the MAID medications or WSLM, the treating physician should administer any ante-mortem interventions required for preservation of organ quality, such as heparin, as required and previously consented to by the patient.

5.C) WLSM procedures

Guidelines for WLSM can be found at: Downar J, Delaney JW, Hawryluck L, Kenny L. Guidelines for the withdrawal of life-sustaining measures. Intensive Care Med. 2016 Jun;42(6):1003-17.

5.D) MAID procedures

Information regarding MAID practice can be found in the Centre for Effective Practice's MAID resource guide:
https://cep.health/clinical-products/medical-assistance-in-dying/

6. Death determination and surgical retrieval of organs

6.A) Circulatory arrest and determination of death

Some DCDD policies may require insertion of an arterial catheter for monitoring and clinicians may advocate for this to verify the loss of circulation. However, this procedure is invasive and may be painful for patients and, as such, many health care professionals may not recommend this practice in the context of MAID/WLSM.

There was consensus that absence of a palpable pulse was not sufficient to determine death; however, many agreed that an intra-arterial catheter, while preferred, should not be mandatory. Alternative methods of death determination suggested by the forum participants included: absence of a pulse combined with one or more of carotid perfusion ultrasound, aortic valve ultrasound, or asystole by EKG monitoring.

Early experience with MAID suggests that death occurs quickly — within 2 to 3 minutes — compared to conventional DCDD after WLSM where warm ischemic time is frequently longer and will often exceed 30 minutes. Since warm ischemic time is a major predictor of graft outcome, it is possible that organs obtained from MAID donors will have better function that those received from conventional DCDD donors.

6.B) Organ and tissue recovery

Immediately following the MAID or WLSM procedure, the deceased patient must be transferred to the OR for organ retrieval. Families and patients must be briefed before the procedure to set expectations that, if organ donation is to proceed, there is a restriction in time after the patient's death for the family to say goodbye.

D. Protections for Patients

To protect the patient who is seeking MAID or WLSM from pressure or coercion to donate, and to promote their ability to provide free and informed consent, several protections were identified.

Separation of the decision to seek WLSM or MAID from the decision to donate organs

There is broad consensus in the literature that the decision to pursue WLSM or MAID should occur prior to, and separate from, the decision to donate organs[14, 23]; however, there is ambiguity as to how this principle should be put into practice.

It is anticipated that organs from DCDD donors who received MAID may have better transplant outcomes than those from WLSM, as it is anticipated their death will be sooner and therefore the organs will be subjected to a shorter warm ischemic time. As such, it is possible that patients who learn this fact may seek MAID over alternate EOL care to improve their chances of donating. This practice conflates the EOL care decision and the donation decision and becomes ethically problematic. MAID should only be provided for the relief of intolerable suffering, not the optimization of organ function for transplantation, even if the desire to improve organ function comes from the patient themselves.

Protection of the consent process

Reinforce the patient's right to withdraw consent to MAID, WLSM or donation

The legislation for MAID requires a reflection period of ten days and that consent be reaffirmed immediately prior to administration of the MAID drugs. There is no legal requirement for reaffirmation of consent for donation.

Capacity

There must be mechanisms in place to assess the capacity of the patient to consent to MAID.[18, 30] Currently, continued capacity is required to re-confirm consent prior to the MAID procedure[4]; however, this issue may evolve over time to allow advance directive for MAID.[27]

Coercion

Risk of coercion is one aspect that is considered when assessing the patient's eligibility for MAID or WLSM. Coercion specific to the decision to seek MAID/WLSM is outside of the scope of this initiative. However, coercion may also be felt by the patient in their decision to donate their organs and protections must be developed and implemented to mitigate the risk of coercion.

As discussed in step 4 of the clinical pathway, there is consensus in the literature that any discussion about organ donation following WLSM or MAID should take place after, and

separately from, the decision for MAID or WLSM.[17, 23, 24, 38] This is to protect the patient from having their decision to die influenced by a discussion about the possibility to donate. Some advised that discussions about organ donation should be facilitated by the organ donation organization or program as opposed to the patient's treating physician[28], while others suggest that the "treating physician, who often has a long-term relationship of trust with the patient, is usually the preferred person to raise the issue of organ donation."[27]

Once a patient has decided to pursue MAID or WSLM, new potential coercive factors may be perceived by the patient. If the patient's treating physician, MAID provider, or MAID assessor is seen as favoring donation, the patient may perceive pressure to consent to donation in order to access MAID, or to avoid disappointing their health care team.25, 38

Separation of clinical teams for the MAID/WLSM and organ donation procedures

The team involved in assessing eligibility for MAID and administering MAID should be separate from the donation team.[14, 16, 19, 20, 26, 27] MAID assessors, in particular, should be cautioned against discussing or advocating for donation. This latter point may protect the patient from feeling that their access to MAID is contingent on their consent to donation.

Directed donation

On rare occasions, patients may request directed donation, that is, to donate their organs to a specific recipient. This situation may exacerbate existing or create new ethical concerns around pressure, influence, and coercion for the patient.[14] A patient may be much less likely to withdraw consent for MAID or delay the MAID procedure if they know a friend or family member is expecting a life-saving transplant of their organs.

However, prohibiting directed donation for conscious competent patients is also ethically problematic. If directed deceased donation is prohibited, the patient may choose to pursue living, rather than deceased, donation as a means to direct their organ to a specific recipient. This would require the patient, who is already suffering, to undergo a painful operation to recover the required organ(s), only to end their lives by MAID or WLSM, thereafter. This practice would be ethically problematic since patients would endure additional suffering to exert their autonomy to donate.[14, 27] Some jurisdictions have, thus, allowed directed deceased donation following MAID or euthanasia on a case-by-case basis.

It is also possible that patients may request living donation, prior to MAID or WLSM, as a means to improve the likelihood for donation to proceed, to ensure optimum organ function in the recipient, and to be able to witness transplant of their donated organ into their loved one before their death[59].

Confidentiality

While monitoring and reporting practices for MAID vary across Canada, regulations governing these practices are intended to protect the privacy of patients and MAID providers.[40] Most

Canadian provinces do not disclose MAID as the cause of death on the death certificate, nor are the names of MAID providers given.

Some patients wish to keep their decision to seek MAID from their family members and friends. However, organ donation has the potential to compromise confidentiality because surgical incisions incurred during surgical retrieval of organs may be discovered by family member's post-mortem. Families may conclude that organs were removed without consent, which could undermine public trust in the organ donation and transplantation system.[14] Questions could also be raised by family members if the patient required admission or transfer to another hospital or institution to facilitate MAID or donation, potentially compromising the patient's confidentiality.

Since confidentiality of their MAID cannot be guaranteed in the event that a patient donates their organs, Transplant Quebec recommends that surgical retrieval of organs not proceed if the patient wishes to keep their decision for MAID and/or donation confidential.[31] However, others have argued that patient autonomy should be respected and donation should be allowed to proceed, despite these risks.[32]

One further question related to confidentiality is whether to disclose to the potential recipient whether the organ offered was donated by a patient who received MAID. While some authors have argued that transplant candidates should have the right to refuse organs based on donor characteristics, as is done in the Netherlands[27], others point out that information concerning the donor's cause of death, including non-assisted suicide, is not routinely disclosed due to reasons of confidentiality. Granting recipients the right to refuse organs from donors who have received MAID would result in non-use of organs and risk further morbidity or mortality of the transplant candidate as well as those on the list.[17]

Support for patients and families

Supports for patients

The events leading up to and following the decision by a conscious competent patient to donate their organs after MAID or WSLM will be challenging and emotional for patients and their families. Supports must be available for patients, and at the request of the patient, for patient's family and friends. Otherwise, patients may feel burdened by the task of serving as an information broker.

In the conventional sequence of care for DCDD, ODO coordinators usually support the needs of family members and act as a resource for questions. Donation by a conscious competent patient after MAID or WLSM is inherently more complex and demands additional time and involvement from patients and their families. However, conscious competent patients, who may reside at home or at a long-term care facility, are environmentally isolated from immediate and direct access to health care professionals to answer questions and provide support.

Support for families

The events leading up to and following the death of a loved one will be very emotional for family members of the patient. Some may find comfort in their loved one's ability to choose the time and circumstances of their death by WLSM or MAID, while others will be uncomfortable with the patient's choice. The same is true for the patient's decision to donate their organs.

In addition to impacts on the donor, donation has impacts on the family. While this topic requires further research, these impacts may include accommodating pre-mortem assessment, in-hospital location of death, and/or the requirement to transfer the patient's body to the OR immediately after death for surgical retrieval of organs.

E. End-Stage Neurological Conditions and Organ Donation Implications

It is expected that the majority of patients choosing MAID will have illnesses, such as disseminated cancer, that make them ineligible to become organ donors. See Table 1. Among those that are eligible to donate, many will suffer from neurodegenerative diseases, such as ALS. Patients with neurological diseases make up approximately 8 per cent of those choosing MAID internationally[9-11], though they comprised a larger proportion in Canada during 2016.

ALS background

ALS is a neurodegenerative disease, which causes progressive degeneration of motor neurons in the motor cortex of the brain and the spinal cord. Common initial presentations of the disease are difficulty speaking, difficulty swallowing, hand weakness, or foot weakness. Wherever the weakness begins, the patient will experience progression of symptoms in that body region and the weakness will spread to involve other body regions. There is no clinical involvement of tissue outside of the brain and spinal cord. Muscle weakness is a secondary effect of the motor neuron degeneration.

While classically described as a motor disease, ALS is now recognized to cause impairment of frontal executive function, social cognition, or behavior, in some patients. On formal neuropsychological testing, 50 per cent of patients with ALS will have frontotemporal cognitive impairments or behavioural impairments. Up to 40 per cent of these will have sufficient cognitive or behavioural impairment to be classified as having frontotemporal dementia.

ALS has an incidence of two to three cases per 100,000 people. The mean age at onset of ALS is late 50s or early 60s but individuals may be diagnosed in their early 20s up until their late 80s. ALS is ultimately fatal with death usually secondary to respiratory failure. The average survival after symptom onset is 2-3 years, but the range of survival after symptom onset is 5 months to more than 50 years.

The diagnosis of ALS is made by a neurologist on the basis of the patient's story, examination findings, electrophysiology results, and other investigations, and by ruling out ALS mimics. Typical ALS physical examination signs are weakness, muscle atrophy, fasciculations, hyperreflexia, spasticity, and other upper motor neuron findings. Unfortunately, there is no single laboratory or electrophysiological test that can confirm a diagnosis of ALS; therefore, a diagnosis of ALS requires an experienced clinician.

About 10 per cent of patients with ALS have familial ALS, while the majority of patients have sporadic ALS, for which there is no known genetic cause or family history. ALS has been associated with pathologic and molecular findings of protein aggregation, oxidative stress, mitochondrial dysfunction, and inflammation.

Management of ALS patients focuses on symptom management, motor function support, nutrition interventions, and respiratory support. Non-invasive ventilation (NIV), invasive ventilation, and mechanical cough assist devices can support patients with significant

respiratory muscle weakness and some patients become dependent on respiratory support 24 hours per day.

Transmissibility of ALS

One factor that must be taken into account when considering organ donation by ALS patients is the risk of transmission to the recipient. Much of the research on this topic has taken advantage of mouse and cell culture models of familial ALS.

Prion-like transmission of ALS in experimental models

Misfolding and aggregation of proteins, such as TDP43 and SOD1, are hallmarks of ALS pathology. Cell cultures experiments suggest that proteins misfolded as a result of ALS-associated mutations may be passed to adjacent cells, providing a hypothetical mechanism from transmission of ALS from donors to recipients.[41-43]

Likewise, cell culture experiments have found that cerebrospinal fluid (CSF) from ALS patients with frontotemporal dementia (FTD), but not non-FTD ALS, can induce aggregation of TDP43 in cultured human glioma cells[44] and another ALS-associated peptide, C9orf72 may also be passed between cells.[45, 46]

In mouse models, researchers have found that homogenized spinal cord tissue from mice genetically engineered to develop ALS (SOD1 mice), was able to induce ALS when inoculated into the spinal cords of recipient mice that also carried the SOD1 mutation; however, no disease was observed in normal mice inoculated with SOD1 homogenates. [41] Experiments in which mice were inoculated with brain or spinal cord tissue from human patients who had died of ALS did not induce disease in these mice.[47]

All of the experiments showing transmission were via proximal contact between brain or spinal cord cells. It is thought the blood-brain barrier, a semipermeable membrane that separates the brain from the periphery and the circulation, may block potential transmission of ALS proteins between transplanted peripheral organs and the brain. Consistent with this, an unpublished experiment connecting a SOD1 mouse to a non-ALS mouse, such that they shared a blood supply, showed no evidence of transmission to the normal mouse (personal communication, Dr. Fabio Rossi).

Evidence of ALS transmission in humans and primates

In the 1970s, brain tissue from deceased patients with amyotrophy and dementia was inoculated into the brains of monkeys. Three of 25 monkeys developed neurodegenerative diseases[48, 49]; however, based on the available case descriptions, the patients with the donated tissue had rapidly progressive dementia. It is possible that these patients had Creutzfeldt Jacob Disease (CJD) with a secondary cause for their amyotrophy, rather than having ALS.

To investigate whether the blood-brain barrier protects against ALS transmission, one study looked at risks of developing neurodegenerative diseases in patients who received a blood

transfusion.[50] They found no increased risk of ALS, Parkinson's, or Alzheimer's, despite the fact that 2.9 per cent received a transfusion from someone who went on to develop a neurodegenerative disease; however, the number of donors with ALS was very low.

Similarly, a study of organ donors with rare disease found no evidence of transmission of neurodegenerative diseases to recipients over five years of observation.[51] It has also been suggested that the extremely low incidence of conjugal cases of ALS, that is cases were two spouses developed ALS, are evidence for non-transmissibility.[52]

However, in a study of 6,190 recipients of human pituitary extracts, three patients died of neurodegenerative pathology attributed to ALS, an unusually high prevalence of the disease.[53] Pituitary extracts are derived from neural tissue and so have the potential to contain the prion-like proteins hypothesized to be associated with ALS. The delay from first injection of pituitary extract to development of ALS-symptoms ranged from 10 to 24 years and the youngest died at 18 years of age. Limitations of this study include difficulty concluding whether these patients actually had ALS, uncertainty whether they received pituitary extract from a cadaveric donor with ALS, and the possibility that the underlying condition of the recipient, for which they were receiving pituitary extract, or some other aspect of their treatment could explain the elevated prevalence of ALS. No cases of Alzheimer's or Parkinson's were observed in this study.

Table 5. Summary of evidence for ALS transmission

Evidence for transmissibility
Cell culture • Prion-like cell-to-cell transmission of misfolded proteins[41-43] • Cerebrospinal fluid (CSF) of ALS patients with frontotemporal dementia (FTD), but not non-FTD, induces protein aggregates[44] Mouse models • Inoculation of spinal tissue from an ALS mouse (SOD1 mouse) into the spine of a recipient mouse causes ALS symptoms, but only in SOD1 mice, not wild type[41] Humans and primates • Inoculation of brain tissue from human patients who had died of neurodegenerative diseases causes disease in 3 of 25 monkeys[48, 49] • Rates of ALS were elevated in recipients of human pituitary extract, which is derived from cadaveric brain tissue[53]
Evidence against transmissibility or null findings
Mouse models • Shared blood supply between ALS and non-ALS mouse did not result in transmission (personal communication with Dr. Fabio Rossi) • Inoculation of mice with brain or spinal cord tissue from human patients who had died of ALS did not induce disease in these mice[47] Humans and primates • No increase of ALS, Parkinson's, or Alzheimer's in patients who received a blood transfusion[50] • No evidence of transmission in transplant recipients followed for five years[51] • No evidence for increased rates of conjugal ALS[52]

ALS patients as organ and tissue donors

There are three ways that an ALS patient could potentially become an organ and tissue donor.

1. DCDD after discontinuation of invasive ventilation
2. DCDD after discontinuation of continuous non-invasive ventilation (NIV) support
3. DCDD after Medical Assistance in Dying (MAID)

Transplantation of organs and tissue from patients with ALS has already occurred with at least 12 cases reported in the literature.[28, 54] At the time of this meeting, at least a further two ALS patients in Ontario have donated their organs. No cases of development of ALS in recipients of organs from ALS donors have been reported.

Opinions from the Canadian ALS research community

Findings of a literature review were presented to the ALS Canada Annual Research Forum on April 30, 2017.[55] The Canadian ALS research community was subsequently asked several questions via Survey Monkey about transplantation of organs from donors with ALS. Forty individuals completed the survey (11 ALS clinicians; 14 basic science researchers; 4 post-doctoral fellows; 4 PhD students, 4 Master students; and 3 who selected 'other'). The results are summarized in Table 6. Importantly, 53.9 per cent supported transplantation of organs from ALS patients, while only 12.8 per cent opposed this.

Table 6. Opinions of the ALS research community on organ donation by ALS patients

Question	Responses			
	Yes	No	Unlikely	Uncertain
Is ALS transmissible through organ transplantation?	0%	7.5%	55.0%	37.5%
Is ALS transmissibility risk different for sporadic vs hereditary ALS?	12.8%	28.2%	18.0%	41.0%
Are certain familial ALS mutations more likely to be transmissible?	21.0%	23.7%	-	55.3%
Should we transplant organs from ALS patients?	53.9%	12.8%	-	33.3%

Conclusions

There are two factors, particular to ALS that should be considered regarding the possibility of organ donation by ALS patients. The first is assessing capacity for informed consent; in particular, whether there is evidence of frontotemporal dementia. This is outside of the scope of this report. The second is the risk of transmission of the disease to the recipient.

With the evidence available, today, it cannot be definitely determined if ALS is or is not transmissible. The rationale and evidence for transmission is strongest for exposure of ALS brain tissue or cerebrospinal fluid (CSF) within the central nervous system (brain or spinal cord) of a recipient. To date, there is no evidence of a transmissible factor for ALS in the periphery of

ALS patients, including all transplantable solid organs. The only evidence for human-to-human transmission comes from the elevated incidence of neurodegenerative ALS-like pathology in recipients of human pituitary extract, which is derived from brain tissue.

One study in mice suggests that genetic vulnerability of ALS, such as SOD1 mutation, may increase the risk of developing ALS through transmission. This suggests that potential recipients with a first degree relative with ALS may be at higher risk of developing ALS from a transplanted organ from an ALS patient. Importantly, evidence for transmissibility in mice is limited to inoculation of central nervous system tissue from sick mice into the central nervous system of recipients. There is no evidence of peripheral transmission.

Finally, if ALS is transmissible through organ transplantation, it will likely take more than ten years for symptoms to develop based on the pituitary extract epidemiological data.

F. System Oversight, Accountability, and Quality Improvement

Offering the opportunity for conscious competent patients to donate their organs after their death by WLSM or MAID will have impacts on institutions, health care professionals, and society. This practice will require mechanisms for oversight, data collection and reporting, and research for quality assurance and improvement to ensure this option for care is performed ethically and safely.

Health care professionals

Professional education

Providers need specialized education and training to communicate effectively with this patient population and to understand the unique challenges that face both the patient and provider in this context. Priority topics for health care provider education include:

a) The law:
    i. MAID eligibility and consent,
    ii. Donation consent by conscious competent patients, and
    iii. Required referral of potential organ donors.
b) Communication strategies for effective and supportive discussions regarding EOL care with conscious competent patients.
c) Processes and procedures for MAID/WLSM and donation.
d) Policies and procedures for when personal conscience or beliefs conflict with the service requested by the patient.
e) Methods for effectively supporting the patient, patient's family, as well as other health care professionals.
f) Strategies to prepare psychologically before and to debrief and seek support after difficult and emotional cases, such as donation after MAID or WLSM.

Professional education should seek to provide health care professionals with tools and knowledge to support and inform patients, to abide by the law and institutional policies, and to be familiar with the procedures involved in MAID/WLSM and donation.

Voluntary participation by health care professionals

While MAID and WLSM are legal in all provinces, some members of the public and health care community do not support these practices. It is possible that the health care professionals involved in the patient's EOL care and donation care, deceased organ retrieval, or the recipients, may have personal or professional objections.

Providing care and support at the patient's EOL care can be an emotional process for health care professionals[24, 25, 28]. This is particularly true for conscious and competent patients, who are able to communicate and develop relationships with health care providers. Donation, MAID, and WLSM each have the potential to add to this difficulty.[28] Thus, it has been argued that participation of health care professionals in donation cases following MAID/WLSM, as with the MAID procedure itself, should be voluntary.[20, 27]

However, accommodating a policy of voluntary participation may be onerous for hospitals and institutions and may risk compromising the fulfillment of the patient's wishes to donate their organs.

Communication and alignment of the health care team

Donation by conscious competent patients will be a rare event for health care professionals. Even those that support the practice may suffer distress and internal conflict if they are not adequately prepared to take part in such a case. Health care professionals participating in donation after MAID should be well informed of the patient's EOL care plan before taking part in the patient's care or meeting with the patient and family.

Conscientious objection

In some instances, health care professionals may object to WLSM or MAID on grounds of conscience or religious beliefs. There is a lack of consensus in the literature concerning the definition, the scope, and limits of conscientious objection to organ donation after MAID/WLSM and a lack of clarity concerning the duty to refer care to another health care provider.[16, 17, 24]

Ideally, patients who are seeking MAID or WLSM should have coordination between all the parties involved in their care, and conscientious objection presents a barrier to this collaboration. The preamble to the Canadian law on MAID states that "everyone has freedom of conscience and religion" under section 2 of the *Canadian Charter of Rights and Freedoms* and states that *"nothing…compels an individual to provide or assist in providing medical assistance in dying".*[4] In some jurisdictions, medical regulatory colleges have established a duty for conscientious objectors to make an effective referral to a willing provider or agent.

Transplant professionals may object, to either retrieving organs or accepting these organs for transplantation, from a donor whose EOL care process involved MAID. However, it is not clear whether conscientious objection should apply in these circumstances as the surgeon is not participating in or facilitating the donor's death. Refusal to retrieve or transplant organs from a donor who received MAID would result in a lost opportunity and non-use of the organs, which would violate the expressed wishes of the patient. These impacts could be mitigated by referring the case to another surgeon within the same centre, or to a surgeon at another centre. In the former case, there may be no effect on allocation; however, in the latter case this may result in the additional use of resources to accommodate the objection. However, if the surgeon refers care to another centre, it may mean that one of their patients, who would have otherwise been first in line for allocation, may be passed over in favor of someone else.

Key themes that emerged from a scoping review of the literature are summarized in Table 7.

Table 7. Key bioethics issues related to conscientious objection

Theme	Summary
Lack of consensus on definition, scope, and limits	• The literature tends to support the notion of conscientious objection for health care providers in general, but there is no consensus on its scope or limits as it applies to organ donation after MAID
The necessity, boundaries, and limits of a duty to refer	• The literature was divided between the position that a conscientiously objecting health care provider should refer the patient to a willing and available provider and the position that any degree of referral as being complicit in a morally wrong act
Participation and cooperation among interprofessional health care providers	• Terms such as participation and cooperation are points of controversy in the MAID literature • Some health care providers, such as nurses and pharmacists, may perceive themselves to be morally implicated in MAID even if they do not directly provide the MAID intervention (e.g. the pharmacist prepares the drugs used to administer MAID)
Tensions between conscience-based refusals and job security	• Some health care providers may perceive that they have no power to conscientious objection to an act they find morally objectionable without risks to their employment
Potential harms to the donor and the transplant candidate	• Scarce literature • Objecting to using organs from MAID donors may lead to death or disability for transplant candidates • Refusal does not respect the dying patient's wish to donate

Society

The organ donation and transplantation system rely on public trust to be successful. Some experts worry that there may be a perception that physicians may not do all they can to save the patient or may offer a deliberately pessimistic prognosis in order to encourage a decision for MAID/WLSM to allow recovery of organs for donation.[24] Such a perception could undermine trust in the entire system. Conversely, offering organ donation to patients who wish to die may enhance public acceptability towards MAID by showing a tangible positive outcome of a patient's decision to die.[16, 24]

Institutions and health care facilities

Double requests for MAID and for organ donation will present challenges to institutions and health care facilities, such as:

a) Development of policies and procedures for double requests for MAID and organ donation;

b) Accommodation of conscientious objections as well as professional role objections;
c) Development of protocols for inter-facility transfers when hospital staff either object to, or are not equipped to perform, organ donation after MAID.

Allocation

In general, allocation of organs from a conscious competent donor should proceed as with any DCDD donor. In cases where the donor has an illness that is known to have a transmission risk, or whether the risk of transmission is uncertain, allocation may be restricted to a subset of transplant candidates whose benefit to burden ratio is more favorable. Health Canada guidelines regarding exceptional distribution for organs from donors with certain risk factors or medical conditions must be followed.[56]

Oversight

MAID oversight

Currently, the reporting and oversight mechanisms vary between provinces. In Quebec, all cases must be reported to a committee representing different colleges and stakeholders to assess whether the case proceeded correctly. If the committee determines non-compliance, it may trigger feedback to the physician or reporting to the institution or college. In other provinces, medically assisted deaths, which are considered to be non-natural, require reporting to the coroner, who may have a role in evaluating whether the MAID process met the standards set by legislation and policy. In some provinces, authorization from the coroner may be required prior to surgical retrieval of organs such as in Ontario. In European jurisdictions, reporting requirements vary but the emphasis of the review process is on feedback and education for the practitioner.[7, 38, 57]

Reporting

It is critical for quality assurance, particularly in relation to transplant recipient outcomes that appropriate and thorough documentation processes are adhered to for all aspects of the MAID-organ donation-transplantation process. One barrier to this objective is the segregation of roles such that MAID assessment, donor assessment and management, and transplantation are managed by separate entities in many jurisdictions.

The federal Minister of Health and/or designated provincial officials are responsible for monitoring MAID procedures under the law. The ODO is concerned with clinical operations in relation to potential donors, such as number of referrals, consent rate, missed opportunities, and patient and family experience with the donation process. The transplant organization is concerned with organ quality, recipient outcomes, and adverse events. Ideally, all of this information should be reported nationally and be accessible to clinicians, administrators, and researchers in a centralized database.

Data elements requested by the forum participants to be collected include:

- Who was present for the approach

- Who was approaching
- Records of approach and the patient's response
- Location of approach
- Consent rate
- Name/consent of coroner/committee contacted prior to donation
- What tissues / organs were recovered
- What tissues / organs were transplanted
- Post-hoc assessment and analysis of risk of coercion
- Transplant complications, infection, graft failures, development of neurodegenerative illness

Research Opportunities

Throughout the workshop, two planning committee members were charged with collecting and recording key questions for future research on the topic of donation by conscious competent patients that arose. The key topics for future research are described as follows:

Clinical and biomedical:

1. Can a method be developed to permit heart transplantation from conscious competent patients while adhering to the dead donor rule?
    - Current barriers include cardiotoxicity of drugs used (in Belgium)
    - International advances in heart DCDD
2. What are the impacts of MAID drugs on the medical outcomes for the transplanted organs?
    - Propofol vs. barbiturates
3. What is the effect on transplant outcomes of giving heparin, corticosteroid, or other drugs?
    - Does timing matter i.e. before or after MAID drugs?
4. What are the medical outcomes of organs transplanted from MAID donors vs. conventional DCDD donors?
    - How does this relate to warm ischemic time?
5. What is the etiology and pathophysiology of various neurodegenerative diseases in order to determine if they are transmissible disease?
6. What is the optimal and acceptable work-up for donor suitability?
7. How should eligibility be defined for high-risk donors (i.e. risk to the recipient)?

Ethical

8. Comparison of directed living donation and directed donation in MAID (theoretical question).
9. How is conscientious objection managed in different centres?

Societal

10. What are the perspectives and opinions of transplant candidates about receiving an organ from a MAID donor?
11. What are the experiences of patients who opt for MAID and organ donation and their caregivers?
    - What about families?
12. Transplant candidate's perspective on the risk of refusing a graft from an ALS donor versus the potential to develop ALS.

Administrative or institutional

13. The history of DCDD and its implementation in Canada to inform the implementation of organ donation after MAID.
14. MAID progression and timelines
    - Rates of request for MAID
    - Time from request to procedure
        - Is this affected by underlying illness?
    - How often is MAID procedure postponed or consent withdrawn?
        - When is decision to postpone or withdraw consent made?
    - How often is MAID denied at the second assessment after approval of the first assessment?
15. Compare consent and consent withdrawal rates between organ donation after MAID and conventional DCDD
16. What are the characteristics/demographics of patients who consent to donation after MAID?
17. Does a routine approach result in more patients providing consent? i.e. Do all or nearly all of those who would consent make unsolicited inquiries?
18. How should the donation approach be made?
    - What skills are necessary?
    - When is the optimal time to approach?
19. How should post-transplant monitoring/surveillance be structured?
    - What data should be collected?
20. Factors influencing the decision to have mandatory reporting?
21. What is the potential donor pool among patients choosing MAID?
22. What are the barriers and the facilitators of organ donation after MAID?
23. Development and implementation of knowledge translation strategies for other professionals (family physician, palliative care community, neurologists and respiratory medicine).
24. What are the psychological impacts for health care professionals to participate in organ donation after MAID?

Appendix 1: Glossary of Terms

Amyotrophic Lateral Sclerosis (ALS): neurodegenerative disease that causes progressive degeneration of the motor neurons in the motor cortex of the brain and the anterior horn cells of the spinal cord.

1. Hereditary ALS: disease is inherited in an autosomal dominant or autosomal recessive manner.
2. Sporadic ALS: disease has not been caused by any genetic mutations known to cause ALS and there is no evidence of other family members with ALS.

Autonomy: Self-legislation; a capable patient is legally and ethically permitted to make health care decisions affecting his or her own body that are consistent with his or her values, wishes, beliefs, and preferences.

Capacity: Refers to the person's ability to understand the information relevant to making a decision about the treatment and to appreciate the reasonably foreseeable consequences of a decision to undergo treatment or not. The law recognizes that capacity can come and go over time.

Clinician-Patient Relationship: the moral foundation of health care and the starting point for treatment and shared decision-making.

Coercion/Undue Influence: *coercion* refers to the practice of forcing someone to do something non-voluntarily by use of force or threat; *undue influence* refers to a person feeling heavily pressured to make a decision, or a series of decisions, that they might not have chosen otherwise. While a decision under undue influence is technically voluntary, the person may report that they have no meaningful choice but to make the decision.

Conscientious Objection: a health care provider who refuses to participate directly in an act because of a private moral or religious belief about that act. Paradigmatic examples in health care include objecting to providing certain forms of reproductive health care (e.g. abortion, contraception) and euthanasia.

Conflict of Commitment/Divided Loyalties: A situation where a person has professional obligations (or loyalties) to a specific person that may be in conflict with loyalties the person has to another person. For example, the treating physician for the organ donor should not also be the treating physician for the potential organ transplant recipient; the physician's loyalties are divided. This is the main reason for separate clinical teams involved in clinical care, organ retrieval, and transplantation.

Conflict of Interest: A situation where the person is in a position to derive personal benefit from actions or decisions made in their professional capacity. For example, the treating physician stands to personally benefit from the death of the patient (e.g., the clinician may benefit financially or materially from the death), and so may not fulfill his or her professional obligations toward the patient as they might otherwise have done.

Consent: consent is a process; a discussion, not an event. The patient must first have the capacity to consent; it must be voluntary, and informed. That is, patients must have the ability to understand and appreciate the potential risks, benefits, and treatment options, likely consequences of the decision or lack of a decision. The consent must relate to the treatment, must be informed, given voluntarily and not obtained through misrepresentation or fraud.

Controlled donation after circulatory determination of death: Controlled DCDD refers to circumstances where donation may initially be considered when death is anticipated but has not yet occurred. This may take place in an ICU or special care unit after a consensual decision to withdraw life-sustaining therapy. Before considering donation, the patient should be judged to have:

- A non-recoverable injury or illness
- Dependence on life-sustaining therapy
- Intention to withdraw life-sustaining therapy, and
- Anticipation of imminent death after withdrawal of life-sustaining therapy.

Dead Donor Rule: i) the removal of organs must not cause the patient's death; ii) the donor must be declared dead by either circulatory or neurological criteria before organs are retrieved.

Directed and Conditional Organ and Tissue Donation: Directed donation is when the capable patient requests that after death his or her organs or tissues are allocated to an identified recipient; conditional donation are conditions the capable patient imposes as to which organs and tissues can or cannot be retrieved after death, or to what designated group of people the organ(s) or tissue(s) should or should not be allocated.

Effective Referral: A referral made by a conscientiously objecting health care provider, in good faith, to a non-objecting health care provider that does not frustrate or impede access to care for the patient. See also *conscientious objection.*

First-person Informed Consent for organ donation: consent for deceased organ donation is obtained directly from the capable potential donor. This is in contrast to the typical practice where authorization for deceased organ donation is sought from the legally appropriate representative, or family members intended to reflect the wishes and values of the dying patient.

Family Override/Family Veto: In circumstances where an individual has complied with the legal requirements for providing valid first-person consent; refers to the practice of respecting a family's objection to organ/tissue donation over the deceased's validly executed consent

Grievous and irremediable medical condition*: A person has a grievous and irremediable medical condition only if they meet all of the following criteria:

(a) they have a serious and incurable illness, disease or disability;
(b) they are in an advanced state of irreversible decline in capability;
(c) that illness, disease or disability or that state of decline causes them enduring physical or psychological suffering that is intolerable to them and that cannot be relieved under conditions that they consider acceptable; and
(d) their natural death has become reasonably foreseeable, taking into account all of their medical circumstances, without a prognosis necessarily having been made as to the specific length of time that they have remaining.

Mature Minor Doctrine: children are entitled to a degree of decision-making autonomy that is reflective of their evolving intelligence and understanding. A minor's right to make such decisions varies in accordance with the individual's level of maturity. The degree to which maturity is scrutinized intensifies in accordance with the severity of the potential consequences of the treatment or of its refusal.

Medical assistance in dying (MAID)

(a)Euthanasia - the administering by a medical practitioner or nurse practitioner of a substance to a person, at their request, that causes their death; or
(b)Assisted suicide - the prescribing or providing by a medical practitioner or nurse practitioner of a substance to a person, at their request, so that they may self-administer the substance and in doing so cause their own death.

Moral distress: the experience that occurs when one believes one knows the right thing to do, but external pressures or constraints make it difficult to fulfill one's ethical obligations or pursue what the person believes to be the right course of action.

Participation: the act of taking part in an event or activity

Prion or prion-like disease: A prion is an infectious agent composed entirely of protein material.

Public Trust: the public trusts health care professionals, and the health system, including the organ donation system, to contribute to their welfare and not take advantage of their vulnerability or compromise their best interests. For example, the public trusts that the treating physician would not attempt to hasten their death—or provide an inaccurately grim picture of their prognosis—in order to retrieve organs. See also *coercion/undue influence* and *conflicts of commitment/divided loyalties.*

Withdrawal of life-sustaining measures: In patients with irrecoverable or life limiting conditions, refers to the consensual decision (between the health care team, patient or surrogate decision maker) to stop life-sustaining treatments (such as mechanical breathing support, artificial airways, cardiovascular support). WLSM is the most common event preceding death in intensive care units.

*An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying) S.C. 2016, c. 3

Appendix 2: Workshop Participants

Ms. Julie Allard; PhD Candidate, Bioethics, University of Montreal, Montreal, QC

Ms. Amber Appleby – Steering Committee; Associate Director, Deceased Donation and Transplantation, Canadian Blood Services, Vancouver, BC

Dr. Cecile Bensimon; Director, Ethics and Professional Affairs, Canadian Medical Association, Ottawa, ON

Mr. Michael Bentley; Manager, Provincial Initiatives, Alberta Health Services, Edmonton, AB

Ms. Kathy Bouwmeester; Vice-President Director Western Region and Chair of Partners Committee, Canadian Association of Critical Care Nurses; Registered Nurse, Peter Lougheed Centre, Alberta Health Services, Calgary, AB

Dr. Daniel Buchman – Steering Committee; Bioethicist, University Health Network; Member, Joint Centre for Bioethics; Assistant Professor, Dalla Lana School of Public Health, University of Toronto, Toronto, ON

Dr. Prosanto Chaudhury; Transplant Surgeon, McGill University Health Centre; Associate Professor, Surgery and Oncology, McGill University; Medical Director, Transplantation, Transplant Quebec, Montreal, QC

Dr. Janice Chisholm; Associate Professor, Anesthesia and Critical Care, Dalhousie University; Anesthesia Program Director, Dalhousie University, Halifax, NS

Mr. Chris Cochrane; Medical Writer, Bearing Biomedical, Vancouver, BC

Ms. Rosanne Dawson; Legal Counsel, Canadian Blood Services, Ottawa, ON

Dr. Laura Donahoe; Thoracic and Lung Transplant Surgeon, Toronto General Hospital, University Health Network, Toronto, ON

Dr. James Downar – Co-chair, Steering Committee; Critical Care and Palliative Care Physician, University Health Network and Sinai Health System; Associate Professor, Department of Medicine, University of Toronto; Chair, Ethical Affairs Committee, Canadian Critical Care Society, Toronto, ON

Mr. Edward Ferre; Director, Program Development and External Relations, BC Transplant, Vancouver, BC

Dr. Marie-Chantal Fortin – Steering Committee; Associate Professor, Bioethics Program, Department of Social and Preventive Medicine, École de santé publique de l'Université de Montréal; Researcher, Nephrology and Transplantation Division, Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM); Chair, Ethics Committee, Canadian Society of Transplantation, Montreal, QC

Ms. Joan Gilmour; Professor, Osgoode Hall Law School, Toronto, ON

Mr. Clay Gillrie – Steering Committee; Senior Program Manager, Deceased Donation, Canadian Blood Services, Vancouver, BC

Dr. Aviva Goldberg – Steering Committee; Head Pediatric Nephrologist, Department of Pediatrics and Child Health, University of Manitoba; Clinical Ethicist, University of Manitoba; Director, Canadian Society of Transplantation, Winnipeg, MB

Ms. Vanessa Gruben – Steering Committee; Associate Professor, Faculty of Law, University of Ottawa; Member, Centre for Health Law, Policy and Ethics, Ottawa, ON

Dr. Andrew Healey; Chief Medical Officer, Donation, Trillium Gift of Life Network; Corporate Division Head and Medical Director, Critical Care, William Osler Health System; Associate Clinical Professor, Department of Medicine, McMaster University, Toronto, ON
Dr. Mark Heule; Medical Director, Intensive Care Unit, Misericordia Hospital, Edmonton, AB
Dr. Dirk Huyer; Chief Coroner, Ontario, Ministry of Community Safety and Correctional Services; Associate Professor, Department of Pediatrics, University of Toronto, Toronto, ON
Ms. Peggy John; Senior Program Manager, Program Operations, Canadian Blood Services, Vancouver, BC
Dr. David Kuhl; Professor, Departments of Family Practice and Urologic Sciences, Faculty of Medicine, University of British Columbia, Vancouver, BC
Ms. Jehan Lalani – Steering Committee; Program Manager, Deceased Donation, Canadian Blood Services, Calgary, AB
Dr. Jean-François Lizé; Respiratory and Critical Care Intensivist, Centre hospitalier de l'Université de Montréal (CHUM); Associate Professor, Université de Montréal, Montréal, QC
Ms. Sandra Martin; Author and Journalist, Toronto, ON
Dr. Linda Panaro; Patient Representative; Ottawa, Ottawa, ON
Dr. Steven Paraskevas; Medical Scientist, Transplant Surgeon, Director of Pancreas and Islet Transplantation, Director of Transplant Research, McGill University Health Centre (MUHC); Associate Professor of Surgery, McGill University, Montreal, QC
Ms. Marie-Noëlle Saint-Pierre; Conseillère en éthique, Commission de l'éthique en science et en technologie, Québec, QC
Dr. Shelly Sarwal; Patient Representative, Halifax, NS
Dr. Michael Sharpe – Co-chair, Steering Committee; Intensivist, London Health Sciences Centre; Professor, Department of Anesthesia and Perioperative Medicine, Schulich School of Medicine, University of Western Ontario; Treasurer, Canadian Critical Care Society, London, ON
Dr. Sam Shemie – Steering Committee; Division of Pediatric Critical Care, Montreal Children's Hospital, McGill University Health Centre and Research Institute; Professor of Pediatrics, McGill University; Medical Advisor, Deceased Donation, Canadian Blood Services, Montreal, QC
Dr. Christen Shoesmith – Steering Committee; Neurologist, Medical Director, London Health Sciences Centre ALS Clinic; Assistant Professor, Clinical Neurological Sciences, Western University; Member, Canadian Neurological Sciences Federation, London, ON
Dr. David Unger; Director and Ethicist, Providence Health Care, Vancouver, BC
Dr. William Wall; Professor Emeritus, Department of Surgery, University of Western Ontario, London, ON
Ms. Sherri Yazdani; Research Associate, Faculty of Law, University of Ottawa, Ottawa, ON
Ms. Kimberly Young; Director, Donation and Transplantation, Canadian Blood Services, Edmonton, AB
Dr. Dirk Ysebaert; Vice-Dean Faculty of Medicine, University of Antwerp; Director, Department of Hepatobiliary, Transplantation and Endocrine Surgery, Antwerp Transplant Center, Belgium

Appendix 3: IPSOS Public Survey

Methodology

ORGAN DONATION IN COMPETENT CONSCIOUS PATIENTS

FIELDWORK DATES	September 13th to 16th, 2016
AUDIENCE	Canadian General Public, aged 18+
LENGTH	7 minutes
METHODOLOGY	Ipsos Canada eNation Online Omnibus

- The Online Omnibus draws on sample from the Ipsos Online Panel and surveys a nationally representative sample of approximately 1,000 Canadians each wave.
- Slight weights were applied to the final data to ensure a nationally representative sample of Canadians by region (excluding Quebec), age, and gender.

Credibility Interval

ORGANDONATION IN COMPETENT CONSCIOUS PATIENTS

1,006 **SAMPLE SIZE**

+/- 3.5 **CREDIBILITY INTERVAL**
at 95% confidence interval

Statistical margins of error are not applicable to online polls. All sample surveys and polls may be subject to other sources of error, including, but not limited to coverage error and measurement error.

The precision of online polls is measured using a credibility interval. In this case, the poll has a credibility interval of plus or minus 3.5 percentage points.

Where figures do not sum to 100, this is due to the effects of rounding.

Significant differences are flagged using ▲▼

	Total	B.C.	Alberta	Saskatchewan/ Manitoba	Ontario	Atlantic
SAMPLE SIZE	(n=1,006)	(n=158)	(n=136)	(n=119)	(n=454)	(n=139)
CREDIBILITY INTERVAL	+/- 3.5	+/- 8.9	+/- 9.6	+/- 10.2	+/- 5.2	+/- 9.5

Canadian Blood Services
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Ipsos

Key Findings - I

- Ninety-two percent of Canadians approve of people donating their organs at the time of their death.
- Support for the idea that a patient who is conscious and competent should be eligible to donate their organs if they decide to withdraw life sustaining treatment (87%) or receive medical aid in dying (80%) remains high, however support is significantly lower than the approval recorded for organ donation in general (92%).
- Older respondents and females were more likely to approve or support organ donation under these circumstances.
- A significantly higher proportion oppose the idea of a patient who receives medical aid in dying donating their organs (12%, compared to 6% who oppose donation after withdrawal of life sustaining treatment and 4% who oppose organ donation in general).
- Concerns of those who oppose organ donation under these circumstances include the risk of the donors' illness being transmitted to the recipient of the organ (48%), the possibility of vulnerable persons feeling pressured to withdraw life-sustaining treatment or choose medical aid in dying sooner than they may have otherwise (46%), or vulnerable persons feeling pressured to donate their organs (43%).

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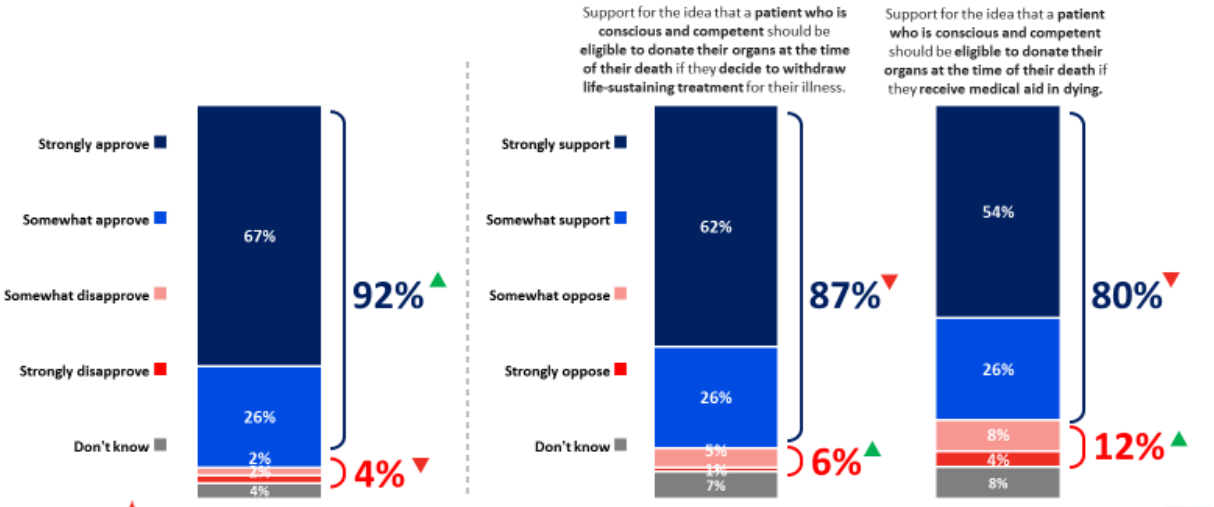
Key Findings - II

- Eight in ten agree that physicians or other qualified medical practitioners should be required to discuss organ donation with all adult patients regardless of illness/condition or end-of life care decision.
- Seventy-five percent of respondents think the decision of who should or should not donate their organs should take into consider both scientific evidence and the concerns of donation recipients.
- The majority agree (83%) that the decision to donate organs should be reconfirmed prior to end-of-life care being administered, however fewer agree (53%) that organ donation should only be discussed AFTER a decision regarding withdrawal of life sustaining treatment or receiving medical aid in dying is made.
- Despite high approval for organ donation overall, as well as high support for donation after end-of-life care is administered, a quarter are undecided about whether they would be willing to accept an organ transplant if there was a possibility the organ was donated by an individual who made the decision to withdrawal life sustaining treatment or receive medical aid in dying.

RESULTS IN DETAIL

Overall, 92% of Canadians approve of Organ Donation after death; Support drops for those who choose end-of-life care

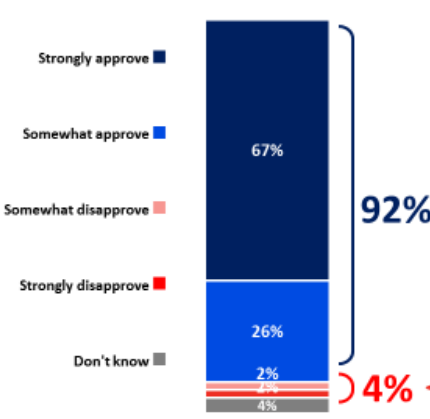


7 Canadian Blood Services It's in you to give

Q. How do you feel about organ donation that is, people donating their organs after death? Do you strongly approve, somewhat approve, somewhat disapprove, or strongly disapprove? / Q. In principle, do you strongly support, somewhat support, somewhat oppose or strongly oppose the idea that a patient who is conscious and competent should be eligible to donate their organs at the time of their death if they decide to withdraw life-sustaining treatment for their illness? / In principle, do you strongly support, somewhat support, somewhat oppose or strongly oppose the idea that a patient who is conscious and competent should be eligible to donate their organs at the time of their death if they receive medical aid in dying? Base: All Respondents (n=1,006)

Ipsos

Overall Approval for Organ Donation After Death



More likely to approve

- Females (95%)
- Aged 55+ (97%)
- Respondents in BC (98%), compared to Alberta (86%), SK/MB (89%) and Ontario (92%)
- Higher income households (96% for households earning $100K+, and 96% for those $60-<$100k), compared to lower income households (89% in households of <$40k)
- Those who support organ donation after withdrawal of life sustaining treatment (97%)
- Those who support organ donation after receiving medical aid in dying (97%)
- Those who would accept a transplant if needed from a donor who made end-of-life decision (96%)
- Agree the decision to donate organs should be based on evidence and recipient concerns (94%)

More likely to disapprove

- Male (6%)
- Younger respondents (peaking at 6% among those who are aged 18-34)
- Respondents in Alberta (9%), compared to BC (1%) and Ontario (3%)
- Oppose organ donation after withdrawal of life sustaining treatment (27%)
- Oppose organ donation after receiving medical aid in dying (16%)
- Those who are undecided if they would a accept a transplant if needed from a donor who made end-of-life decision (7%)
- Agree the decision to donate organs should be based on recipient concerns (7%)

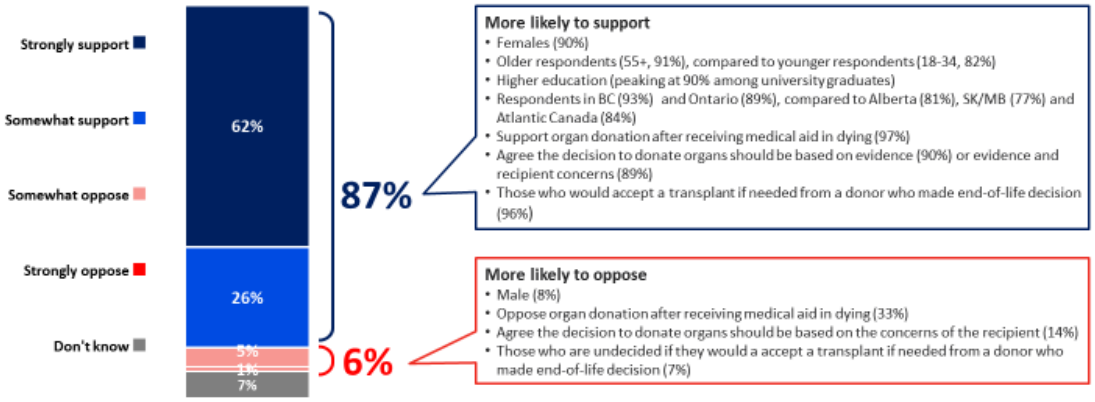
8 Canadian Blood Services It's in you to give

Q. How do you feel about organ donation that is, people donating their organs after death? Do you strongly approve, somewhat approve, somewhat disapprove, or strongly disapprove?
Base: All Respondents (n=1,006)

Ipsos

While support remains strong, fewer support the idea of a conscious and competent patient donating their organs if they decide to withdraw life-sustaining treatment

Support for the idea that a **patient who is conscious and competent** should be **eligible to donate their organs at the time of their death** if they **decide to withdraw life-sustaining treatment** for their illness.



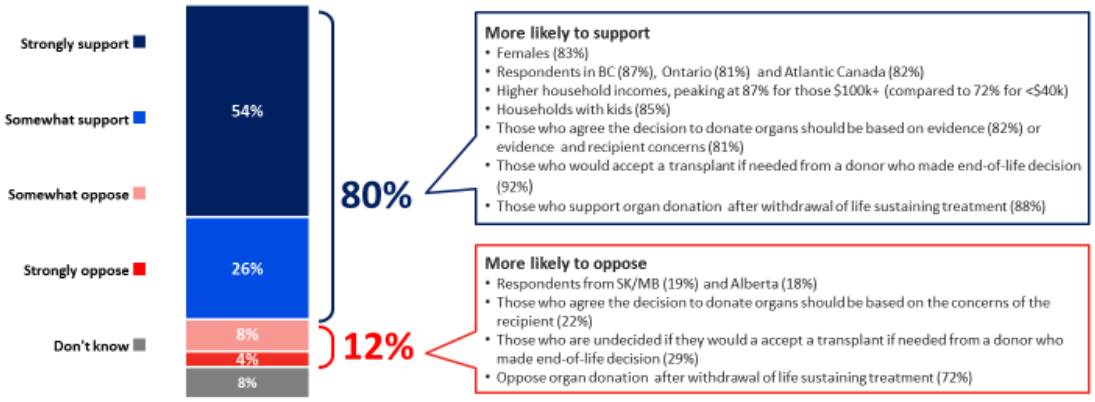
Canadian Blood Services *It's in you to give*

Q. In principle, do you strongly support, somewhat support, somewhat oppose or strongly oppose the idea that a patient who is conscious and competent should be eligible to donate their organs at the time of their death if they decide to withdraw life-sustaining treatment for their illness?
Base: All Respondents (n=1,006)

Ipsos

Support is lower for the idea of a conscious and competent patient donating their organs if they decide to receive medical aid in dying

Support for the idea that a **patient who is conscious and competent** should be **eligible to donate their organs at the time of their death** if they **receive medical aid in dying?**



Canadian Blood Services *It's in you to give*

Q. In principle, do you strongly support, somewhat support, somewhat oppose or strongly oppose the idea that a patient who is conscious and competent should be eligible to donate their organs at the time of their death if they receive medical aid in dying?
Base: All Respondents (n=1,006)

Ipsos

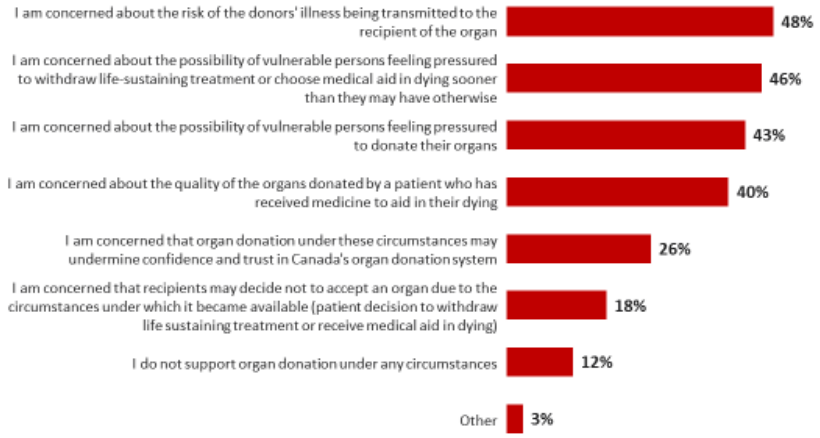
Paramount concerns include risk of patients illness being transmitted to recipient via organ and pressure on vulnerable patients to end care or choose organ donation

6%

OPPOSE IDEA OF ORGAN DONATION AFTER WITHDRAWAL OF LIFE-SUSTAINING TREATMENT

12%

OPPOSE IDEA OF DONATING AFTER RECEIVING MEDICAL AID IN DYING

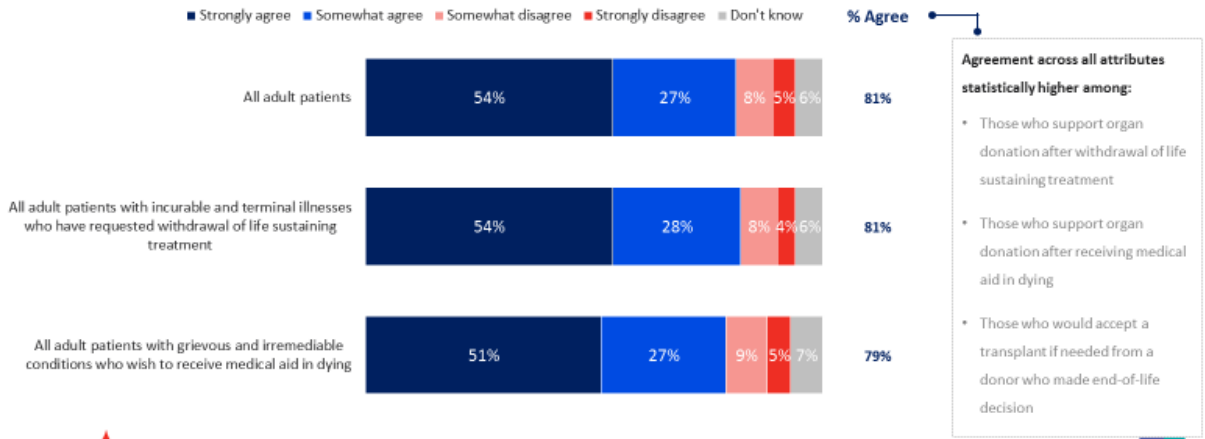


11 Canadian Blood Services *It's in you to give*

Q. If you believe a patient in these circumstances should be prevented from donating his or her organs, please indicate your concerns.
Base: All Respondents (n=139)

Ipsos

The majority agree that qualified medical practitioners should be required to discuss organ donation with all adult patients, regardless of illness/condition or end-of life care decision

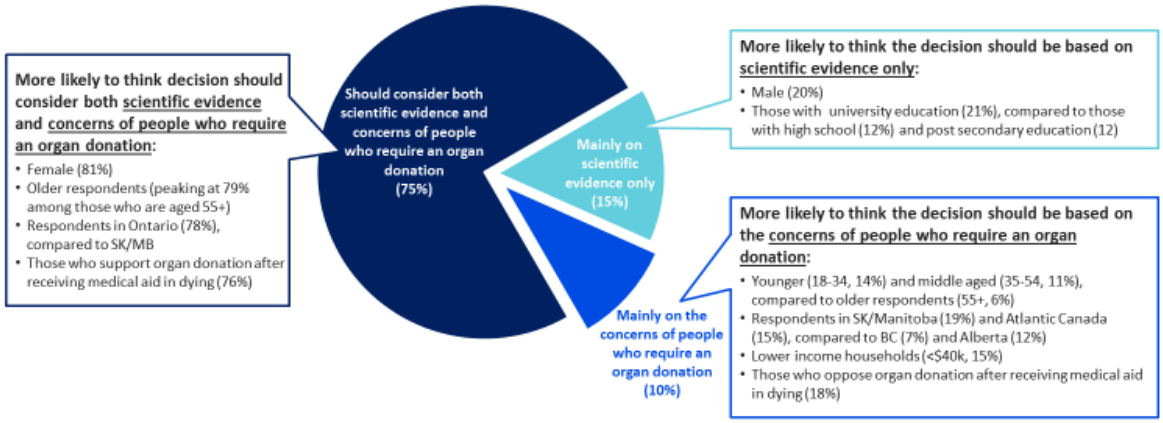


12 Canadian Blood Services *It's in you to give*

Q. Do you strongly agree, somewhat agree, somewhat disagree or strongly disagree that physicians or other qualified healthcare practitioners should be required to discuss organ donation with....
Base: All Respondents (n=1,006)

Ipsos

Three quarter of respondents think that deciding who should or should not donate their organs should take into consideration both scientific evidence and concerns of recipients

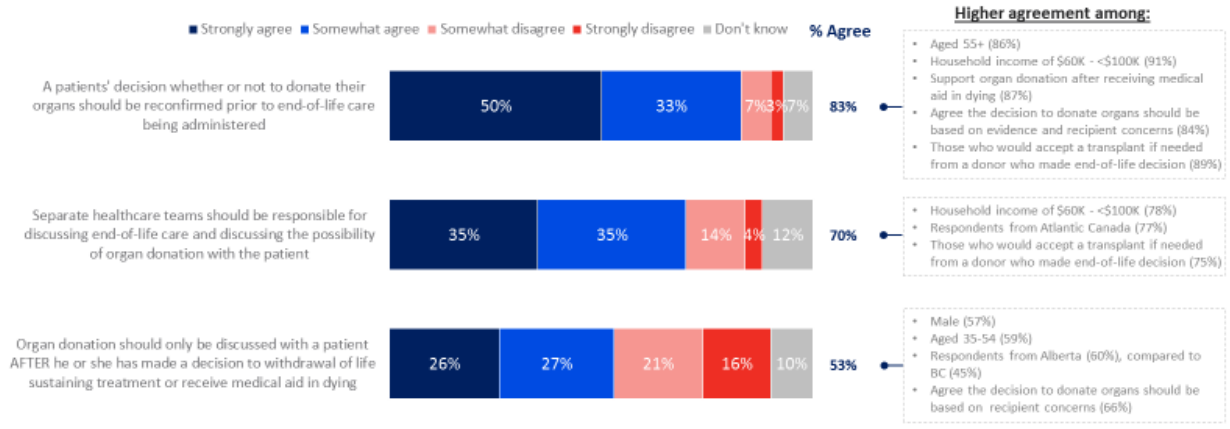


13 Canadian Blood Services It's in you to give

7. Do you think that deciding who should or should not donate their organs should be based....
Base: All Respondents (n=1,002)

Ipsos

While the majority agree the decision to donate should be reconfirmed prior to end-of-life care being administered, fewer agree the option should be discussed only AFTER this decision is made



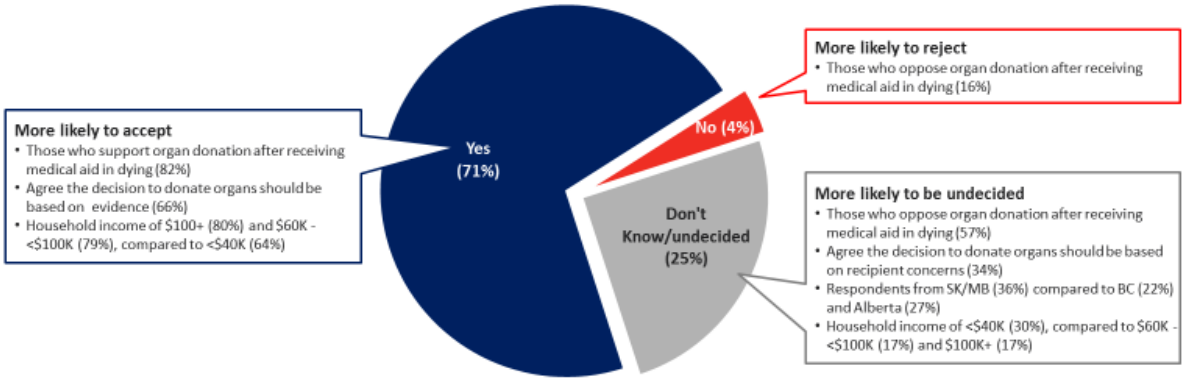
14 Canadian Blood Services It's in you to give

8. To what extent do you agree or disagree with the following?
Base: All Respondents (n=1,006)

Ipsos

The majority would accept an organ donation even if the organ was donated by an individual who decided to engage end-of-life measures; a quarter are undecided

Would you be **willing to accept an organ transplant** if there was a **possibility the organ was donated** by an individual who made the decision to **withdrawal life sustaining treatment** or receive **medical aid in dying**

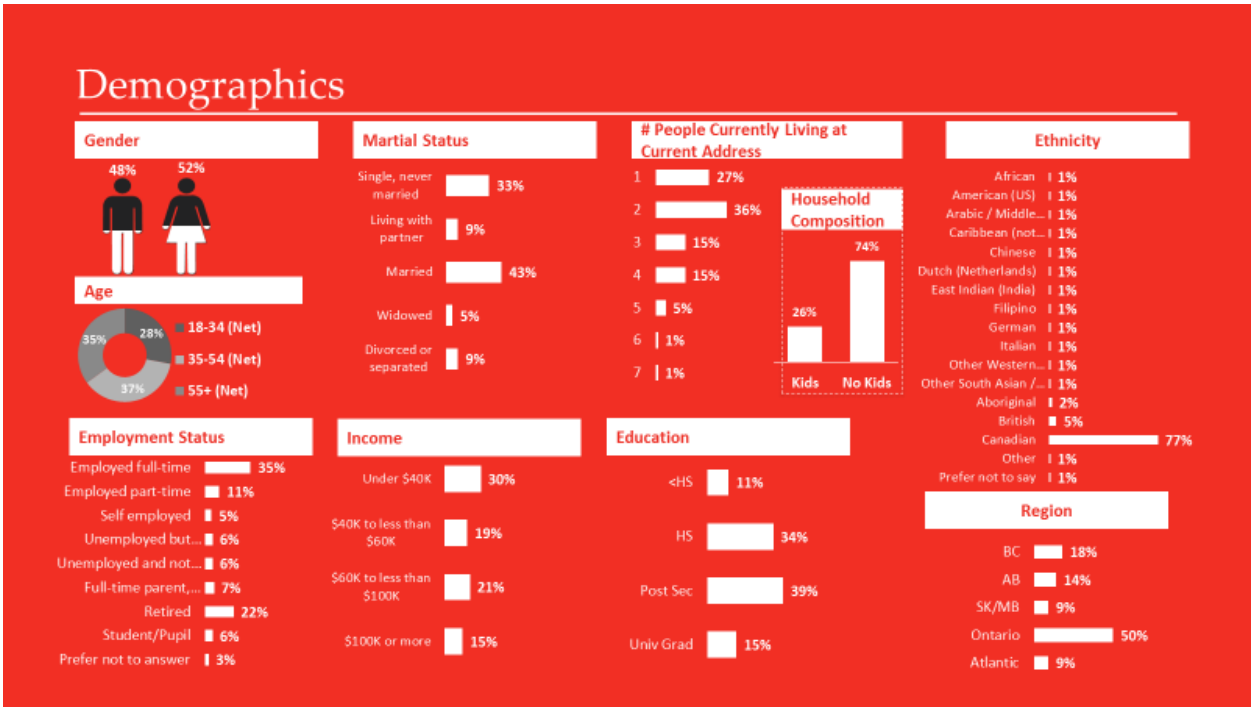


15 Canadian Blood Services *It's in you to give*

9. If you were in need of an organ transplant, would you be willing to accept one if there was a possibility the organ was donated by an individual who made the decision to withdrawal life sustaining treatment or receive medical aid in dying?
Base: All Respondents (n=1,006)

Ipsos

Demographics



Appendix 4: Organ Donation in the Conscious Competent Adult – A Scoping Review

What do we know about deceased organ donation by the conscious, competent adult? A scoping review.

Ms. Vanessa Gruben, Ms. Sherri Yazdani & Dr. Aviva Goldberg

A. Introduction

Organ donation after cardiac death (DCD) has been practiced in Canada since 2005.[1] Only controlled DCD is practiced in Canada, whereby donation occurs following the decision to withdraw life-sustaining treatment from a patient who has a serious illness and is not expected to have meaningful recovery. Most commonly these patients are in an intensive care unit (ICU) after suffering a devastating brain injury, and accordingly are unconscious prior to death. In these cases, authorization to proceed with DCD is given by the patient's substitute decision maker or family, who may or may not be aware of the patient's wishes regarding organ donation. Yet there are some patients who are conscious, competent and capable of actively making decisions regarding their end-of-life care, whether death occurs through the withdrawal of life-sustaining measures (WLSM) or medical aid in dying (MAID). These individuals may also wish to donate their organs after death. While there have been reports of both groups of patients requesting organ donation following WLSM or MAID,[2,3] only two provinces, Quebec and Ontario have created guidelines specific to organ donation after MAID.[3]

The right of a competent adult to refuse medical treatment (even when the consequence of that refusal may lead to death) has been established for many years, and it is accepted that life-sustaining therapy can be discontinued when its burdens outweigh its benefits, so death after WLSM is a routine part of ICU practice.[5] The legalization of MAID in Canada as of June 2016 will certainly increase the frequency with which a conscious competent adult may request organ donation as part of his or her end-of-life care. Following the Supreme Court of Canada's decision in *Carter v Canada*,[6] the federal government passed legislation amending the Criminal Code to allow eligible Canadians to request MAID. To be eligible, an individual must be 18 years of age and capable of making health care decisions, have a grievous and irremediable medical condition as defined by the legislation, have made a voluntary request for MAID that is not the result of outside pressure or influence and give informed consent to receive MAID.[7] The legalization of MAID requires us to consider whether and how organ donation after MAID should proceed.

This paper considers deceased organ donation by conscious, competent patients, including those who request WLSM and those who choose MAID. Although these patients have chosen different end-of-life measures, these patient groups are similar in that they are able to provide first person informed consent for organ donation. Several ethical and practical considerations arise in these circumstances, which should inform policy making. The purpose of our study was to determine and synthesize the range of research on this subject and to disseminate our research findings to ethicists, clinicians and policy makers who are seeking to develop policies to guide deceased organ donation following the withdrawal of life-sustaining treatment or medical aid in dying.

B. Methods

We employed the framework for scoping reviews designed by Arksey and O'Malley[8] and Levac et al.[9] Our focus was on the ethical and legal analysis of organ donation by a conscious, competent adult following either the withdrawal of life-sustaining treatment or MAID. We selected four databases: PubMed, SCOPUS, Legaltrac and LexisNexis Quicklaw.

Literature search

We first reviewed a limited number of sources to establish a review question and identify relevant keywords. We identified three concepts which were expanded into categories of keywords. The first concept was organ donation, the second related to the capacity of the potential donor and the third addressed either the patient's underlying condition or the request for WLSM or MAID. We then developed a search strategy to examine English-language academic sources, searching each database for articles which included a keyword from the organ donation concept and any keyword from either of the other two concepts in their title or abstract. We consulted an academic librarian who verified the validity of the search strategy.

In addition, we checked the bibliographies and citations of the studies selected for inclusion for further articles to be included in the scoping exercise. At this stage, we identified further references (n = 3) after which we reached saturation where no new studies were identified.

Screening

Results were screened for inclusion and exclusion criteria. Ms. Vanessa Gruben and Ms. Sherri Yazdani screened titles and abstracts to develop eligibility criteria.[8] We included only English language journal articles that were peer-reviewed. Articles were excluded if it focused on (1) concepts not related to organ donation; (2) gamete extraction or ovarian tissue donation; (3) family (third person) consent to posthumous donation; (4) non-human organ or tissue donation; (5) medical assistance in dying/euthanasia; (6) consent to living donation; (7) medical/scientific aspects of donation; (8) presumed consent systems. Where abstracts were not available, the full text was screened. Disagreements about eligibility were resolved by discussion and consensus.

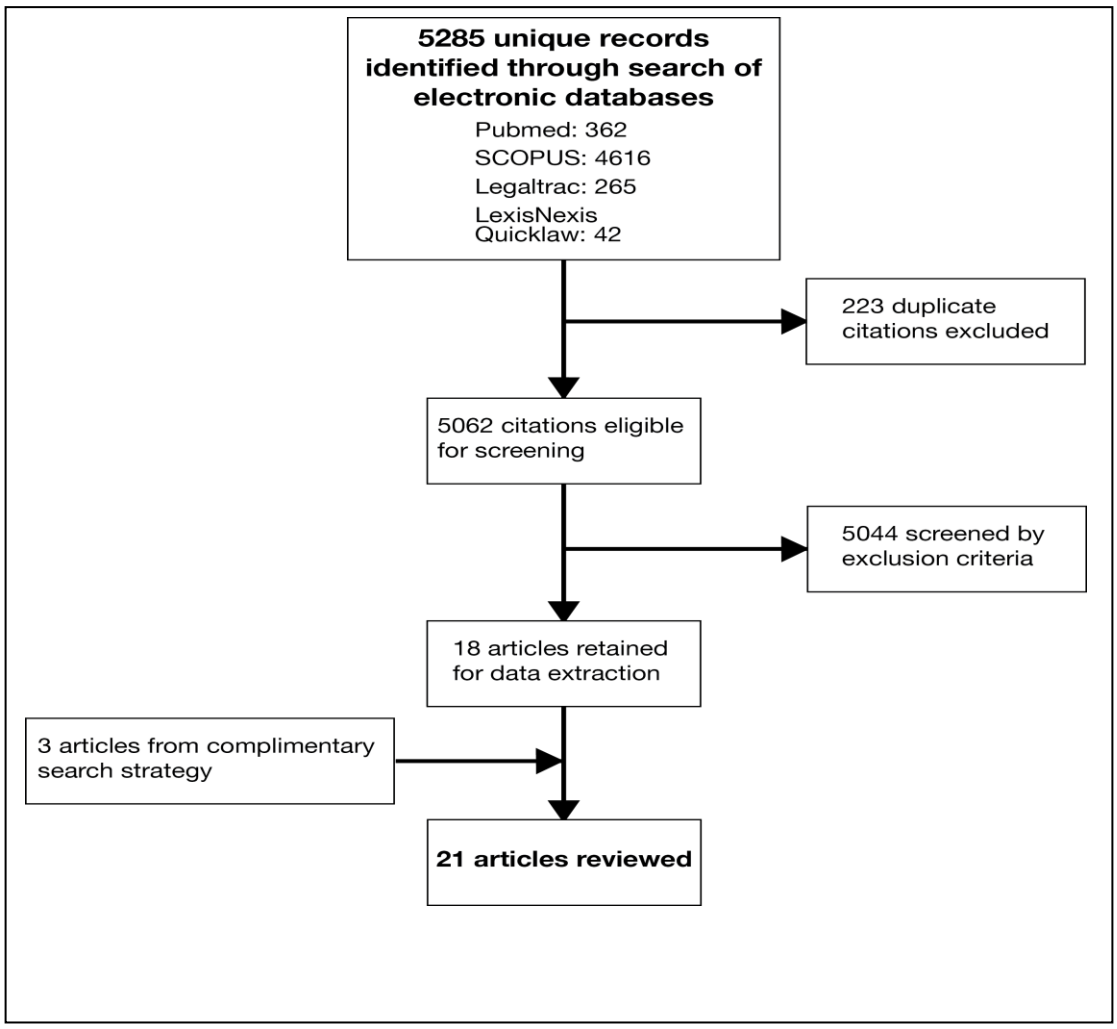
Data Extraction

We charted the data extracted from the articles in a shared spreadsheet. All three authors read each of the articles in full. The process of identifying themes emerging from the relevant sources is an important part of the charting process for scoping reviews.[8] This was an iterative process where additional themes and issues were identified throughout the charting process. We each identified emerging themes and issues and held a series of team meetings to finalize the overarching themes.

C. Results

Figure 1 summarizes the search results and screening process. Of the 5,062 identified articles, 18 articles were included in the scoping review along with 3 articles identified by a complementary search of citations. Included articles were published between 2009 and 2016 from academic articles and one book chapter. The included articles yielded information on the experience in Canada (2) as well as the United States (6), Australia (1), the United Kingdom (1), Switzerland (2), the Netherlands (4) and Belgium (5).

FIGURE 1. Flowchart of the identification and screening process.



Eight overall themes emerged from the literature: (1) rationales for and against deceased organ donation following MAID/WLSM; (2) ethical considerations arising for deceased organ donation by the conscious competent

Eight overall themes emerged from the literature: (1) rationales for and against deceased organ donation following MAID/WLSM; (2) ethical considerations arising for deceased organ donation by the conscious compete

patient; (3) practical considerations arising for deceased organ donation by the conscious competent patient; (4) possible protections for the patient considering deceased organ donation; (5) considerations governing the approach; (6) public perception of deceased organ donation in the conscious competent patient; (7) organ donation euthanasia; (8) general observations with respect to international experience of organ donation coupled with either WLSM or MAID. Several issues were identified within each theme. See Overview of Themes & Issues below.

While a complete summary of the range of issues and themes identified are contained below, only those relevant to the current policy discussions in Canada are discussed herein. For example, organ donation

euthanasia is not discussed as this is currently not being proposed or considered. Further, data extracted under the theme of general observations with respect to international experience have been included under discussion of other themes, where appropriate.

Rationales for and against deceased organ donation following MAID/WLSM

The literature revealed rationales both in support of and against organ donation following WLSM or MAID. Most commonly, it was argued that permitting organ donation by the conscious competent adult could increase the number of organs available for donation[10-20] and indeed, many of these organs would likely be of better quality than those using a conventional DCD procedure[16]. Respect for individual autonomy and self-determination was also a paramount consideration supporting organ donation by those who are undergoing WLSM or MAID.[10, 12-13, 21-24] Under these unique circumstances, the patient can give first-person informed consent to organ donation after death and as such the patient's wish to be an organ donor should be respected. In addition, respecting a patient's wish to be an organ donor may be of personal benefit to the donor, whose own death may easier to bear if he or she knows that death will save or improve the life of another[13, 24] and it may likewise benefit his or her family by providing increased solace or comfort during their grieving [13, 24]. Two authors cited cost-effectiveness as a factor in favor of permitting organ donation in these circumstances.[12, 20] Finally, as is discussed below, others noted that this approach may increase public acceptance of assisted dying.[20]

By contrast, it has been argued that permitting organ donation under these circumstances may unduly pressure patients; a person who may not otherwise opt for MAID might choose to die to donate his or her organs to help others.[12] A related concern is that the patient may feel that they need to consent to organ donation because he or she is dependent on his physician to withdraw treatment[21] (this concept is discussed further in the section "Ethical considerations" below)

Beyond the pressure which may be experienced by individuals, there is a concern that permitting organ donation following WLSM or MAID could undermine public trust in the organ donation system because "physicians would be tempted to be deliberately pessimistic about the patient's prognosis to enhance the patient's chance of requesting withdrawal of treatment".[21] Further, one author urged caution: the fact that combinations of euthanasia and organ donation have already been performed does not necessarily create justification for it.[25]

Ethical considerations

Several ethical considerations have been raised with respect to the possibility of organ donation following WLSM or MAID. First, there is a concern that the patient may be subject to undue influence or coerced to donate his or her organs.[10, 12, 21, 23] There are a range of external factors that could influence the patient's decision: a patient may feel pressured to consent to donation because he or she is dependent on a physician for withdrawal of care whom the patient may perceive as favoring donation;[21, 25] patients may choose to die in order to donate their organs to save the lives of others[12-13, 23-24] or may choose to end their lives earlier than they would otherwise, in order to donate.[13] Some authors contend that the act of informing patients of the opportunity to donate could put pressure on a patient.[10, 20, 25] The pressure on the patient's decision-making may be exacerbated if they are aware of a specific recipient in need of an organ.[23] In this vein, some note that the request for MAID should be motivated by the suffering of the person considering MAID, not organ donation to a specific recipient, such as a relative,[10, 23, 25] or more generally.[10] Thus, it is crucial that the motivations for consenting to WLSM, MAID and donation are carefully explored by the health care provider as part of the evaluation process. While it is important to ascertain a patient's motivations, the Dutch practice manual warns against discouraging a patient's altruistic intentions if he or she otherwise meets euthanasia criteria: donation should not be discouraged or disallowed solely because a patient expresses altruistic motivation.[23]

Several ethical issues specific to medical staff and health care professionals are raised in the literature. There is a recognition that end-of-life care is often an emotional process for health care professionals.[20-21, 24] Organ donation in the conscious competent adult may be more emotionally difficult for health care professionals, in part, because many of these patients are still able to communicate and bond with the staff, unlike permanently unconscious patients.[24] As such, several authors emphasize the importance of voluntary participation by health care providers.[16, 23]

Not all health care professionals may want to participate in organ donation after MAID or WLSM**.** Health care professionals and hospitals may object on the basis that they are opposed to MAID, and that participation in organ donation after MAID may be tacit endorsement.[12-13, 20] The emotional component of dealing with a person who is currently awake and communicative but is imminently dying may also be playing a role, as discussed above. However, some have questioned the legitimacy of objection to organ donation following WLSM or MAID on the basis that it "could contribute to avoidable patient deaths".[13, 12]

The Canadian public is not unanimous in its support of MAID, and some object to the practice on religious or ethical grounds. Potential recipients who oppose assisted dying may object to receiving an organ from a patient who has undergone MAID, though others may find this acceptable. Some argue that potential recipients should be informed that their donor underwent MAID since, in certain jurisdictions recipients and their physicians have the opportunity to refuse certain types of donor organs for other reasons, such as donor age and lifestyle factors that could increase risk of infectious diseases transmission.[23] Some maintain that the source of the organs should not be disclosed.[13] Not only is detailed information about the circumstances of a donor's death, including a violent non-assisted suicide, not generally disclosed to potential recipients in certain jurisdictions, giving recipients the chance to refuse organs on these grounds would "lead to organ wastage and indeed to the potential death of the recipient".[13] Notably, this practice varies by country. In Belgium, the law prevents disclosing any donor information to the recipient, including the cause of death ,[15] while in the Netherlands both recipients and their physicians may refuse certain types of organs at the time of being placed on the waitlist, and it has been recommended that organs procured following euthanasia also be permitted to be refused in this manner.[23]

Practical considerations

The literature also identifies several practical considerations that must be addressed in any guideline or policy governing organ donation following WLSM or MAID. These range from additional steps or changes in end-of-life care to various medical and clinical considerations which engage both health care providers and institutions.

There are additional steps or modifications to the patient's end-of-life care that will arise if he or she opts for organ donation. There are preparatory procedures that the patient who consents to organ donation may need to undergo including blood tests and imaging to determine whether the organs would be suitable for donation and to prepare for allocation.[16, 23] These may result in increased stress[10] or discomfort.

In addition, the patient may consent to a series of pre-mortem interventions, such as the administration of heparin, which will maintain/improve the quality of his or her organs.[10, 23] While some have indicated that because the patient has provided first-person consent to pre-mortem interventions there is no cause for concern,[10, 20, 26] others have expressed worry about undertaking pre-mortem procedures in this context. The approach to pre-mortem interventions for a patient who has opted for MAID differs as between Belgium and the Netherlands. In Belgium, physicians can administer heparin to the patient on the basis that administering heparin will not harm the patient because he or she will die because of the

euthanasia drugs.[15, 25] By contrast, in the Netherlands, any treatment which is meant to keep the patient's organs in good condition is not permitted[25] as it is generally understood that donation should not interfere with the euthanasia process.[23]

Second, for those who opt to donate their organs, the place of death must be in hospital as opposed to at home.[10, 12, 16, 23, 25] The patient must be hospitalized to facilitate optimal organ recovery and optimize transplantation success for the organs.[13, 23, 25] This may deter the patient from donating, as many patients wish to die at home or in some other "peaceful setting".[13] However, the Dutch and Belgian experience appears to indicate that patients who wish to donate their organs do not see dying in hospital as an obstacle.[25]

Third, the decision to donate one's organs may impact the family's opportunity to say goodbye to their loved one and to grieve their loss[10, 23, 25] as the patient must be transported to the operating room immediately after the physician has determined death.[25] To facilitate this grieving process, in the Netherlands it is recommended that a nurse and second transplant coordinator be available to assist the relatives, and that a private family room be made available for the family.[23] Again, experience demonstrates that this is not seen as an obstacle by patients or their families.[24-25] Indeed, many families "appear very supportive of the patient's last wish despite the potential extra burden."[25]

From the clinician's perspective, organ donation following WLSM or MAID also raises several practical issues. As discussed above, organ donation following WLSM and MAID, involves donation after cardiac death (DCD). In the Netherlands (as in Canada), circulatory death is determined by recording the absence of an intra-arterial pressure wave or some other current method of monitoring circulation followed by a no-touch period of 5 minutes.[23] Some have questioned whether this no-touch period is necessary "given that the patient wants to die and is unconscious".[12-13] Others have noted that the short pre-mortem ischemic time associated with donation after MAID is a potential advantage over donation after WLSM.[13]

Other clinical/medical considerations that arise in this context include confirming eligibility for donation as well as MAID. Both in terms of eligibility to donate (for example, patients who have a metastatic malignancy or other potentially transmissible disease are not eligible to donate)[12, 16] and capacity to consent (e.g. "confirming that the individual has a fatal neurological illness, screening for and treatment of depression, and recognition that some patients have depression, pseudo-dementia or dementia.")[24] Indeed, one author notes "it is imperative to discuss what to do if the patient's condition deteriorates and the patient becomes unconscious in the days preceding the day of the procedure."[23]

Recognizing that donation under these circumstances is still quite new, several articles identify the need for increased cooperation between health care providers and institutions responsible for end-of-life care, organ procurement and transplantation.[13, 16] For example, in one case report, the doctors and nurses in the ICU had no previous relationship with the patient, accordingly the nursing home physician who was performing the euthanasia was temporarily appointed to the hospital.[16] Other suggestions for optimizing care include: ensuring that a transplant coordinator is present during the meeting between the patient and the physician performing the withdrawal or MAID;[23] and creating specialized centres where organ donation following WLSM and/or MAID is performed.[16] In cases where the coroner is involved because of the manner of death, as is required in the Netherlands, it is important that the transplant coordinator make arrangements with the coroner in advance to ensure that permission to use the body for organ donation is granted.[23]

Another practical consideration is the need for supports or debriefing mechanisms for health care professionals and medical staff who participate in these cases. As discussed above, these cases can be emotionally difficult.[24] An American article reported the responsible nurse as stating, ''This was one of

the most intense and difficult things I have done as a nurse, but ultimately certainly also very rewarding knowing that I helped ensure his comfort and some other people's lives will be improved as a result of organ donation.''[24]

Protections for patient/potential donor

The literature identifies several protections to safeguard the interests of the patient and to ensure that they provide free and informed consent to either the withdrawal of life-sustaining measures or MAID as well as organ donation. Although it may be "difficult to disentangle patients' motivations for requesting MAID", the separation of the two decisions is important to help ensure that the request is not solely motivated by organ donation.[10] Indeed in Belgium, legal regulations require that a discussion on the possibility of organ donation can only occur after the request for euthanasia has been granted .[19] In service to this separation of decisions and processes, a number of articles advocate for ensuring separate teams for the WLSM or MAID procedure and the organ donation procedure.[10, 12, 15-16, 22-23] Further, separate medical teams protect the patient from the pressure discussed above, whereby they may feel it is necessary to consent to donation in order to secure the assistance of the physician providing the WLSM or MAID.

With regard to informed consent, health care providers should be particularly alert to the possibility that a patient might be requesting withdrawal or MAID because he can donate organs either to someone specific[23] or in general. He/she may be motivated by some other outside influence, such as financial considerations.[26]

Several authors suggest prohibiting directed donation in this context (e.g. to a friend or family member who the MAID patient knows needs an organ). This addresses the concern that some patients might be motivated to undergo WLSM and/or MAID to donate organs to a specific recipient.[10, 23] However, it has been argued that it may be difficult to prohibit directed donation, as living organ donation is mostly directed and there is no explicit prohibition on directed deceased donation in Canada.[10] Indeed, the Dutch Practice Manual points out that it is illogical that a patient undergoing euthanasia could designate a recipient by choosing to undergo living donation in advance of euthanasia, but that they would be prohibited from directing their deceased donation.[23]

In addition, the health care team must ensure that the patient has sufficient capacity to consent to WLSM/MAID and organ donation.[14] Capacity may be affected by medications that may cloud their cognition and lowering sedation may improve decision-making but could cause the patient distress.[14] There may also be concerns about a patient's decisional duration. Medical staff, health care professionals, family members and possibly a psychiatric consultation will play important roles in assessing the patient's capacity.[26] A waiting period will provide the patient with an opportunity to reconsider or withdraw consent to WLSM/MAID and/or organ donation.

The "approach"

The literature addresses a number of considerations regarding which patients considering WLSM or MAID should be approached about organ donation and how the approach should be made. The literature is divided. Some maintain that all patients in these circumstances should be informed about the possibility of donating their organs[10, 19, 25] since this would support autonomy and justice by giving all potential donors the information with which they could make an informed choice.[10, 23] By contrast, some argue that providing all patients with this information could be perceived as pressuring the patient to donate.[10] To date, no jurisdiction requires that every patient considering WLSM or MAID be informed of the possibility of organ donation. In Ontario, Trillium Gift of Life Network has issued a guidance document which states that approval to receive medical assistance in dying constitutes an "imminent death" and requires designated facilities to notify TGLN so that the individual may be approached.[26] In

the province of Quebec, there is disagreement between the CEST and Transplant Quebec regarding whether the patient should be approached.[10] In the Netherlands, the attending physician is responsible for deciding whether to inform the patient who is considering MAID.[10] One factor that the physician may consider in making this decision is whether the patient has previously registered as an organ donor, as those that have registered would likely be more open to the discussion /approach for organ donation after MAID.[23, 25]

There is a consensus in the literature that where the physician chooses to discuss organ donation with a patient in these circumstances, this discussion should occur *after* the discussion regarding withdrawal of life-sustaining treatment or MAID.[13, 19-20, 25] Making a request before this time may be seen as influencing the patient's decision regarding withdrawal of life-sustaining treatment or MAID or the physician may be perceived as having a conflict of interest.[20] The latter is especially concerning in the context of MAID where the patient may believe that the physician is "only willing to perform euthanasia because the patient will donate organs."[25]

The literature also notes that the discussion about organ donation should be facilitated by the organ procurement team as opposed to the patient's treating physician.[24] Whereas others have suggested that "[t]he treating physician, who often has a long-term relationship of trust with the patient, is usually the preferred person to raise the issue of organ donation."[23]

Public perception

The literature also addresses the potential impact (both negative and positive) of organ donation following WLSM and MAID on both the organ donation system and the practice of MAID. While there is no empirical data on public perceptions of organ donation following MAID in Belgium or the Netherlands, there has been some speculation regarding both the potential impact and mechanisms that should be introduced to bolster public trust in this context.

Some have speculated that organ donation following MAID may "enhance the social acceptability of [assisted dying] practices."[12, 20] However, there is also a risk that the "association of [organ donation and transplantation] with [assisted dying] could reduce the overall acceptability of [organ donation and transplantation] and possibly damage the trust and confidence that societal members currently have in standard/traditional organ donation and transplantation practices."[20] This may be because there is a perception that conflicts of interest may exist as discussed above.[14, 21]

These concerns may be mitigated. Most importantly is the fact that there is first-person informed consent to organ donation in this context.[20] Others have emphasized the importance of transparent, consistent processes to promote public trust in the system.[11, 14] A key process that has been identified which promotes public trust (in addition to patient autonomy) is the separation of the decisions regarding MAID and donation.[10] Others have called for adequate checks to be put in place to ensure that this process unfolds as intended.[19] Current checks exist in other jurisdictions including a notification and request for permission to a coroner or public prosecutor to obtain the body for organ donation,[16, 23] as well as a review by a regional euthanasia committee.[23]

D. Discussion

This scoping review of 21 references revealed important themes and issues in the literature. Notably, the literature overwhelmingly suggests that organ donation after WLSM or MAID is ethically and legally acceptable. It also demonstrates that a number of patients who chose/consented to WLSM or MAID have spontaneously requested to donate their organs.

The bioethical and practical considerations governing organ donation following WLSM or MAID generated significant discussion in the literature. Bioethical concerns arose with respect to the dying patient, the medical staff and the recipient. Many authors expressed concern about the possibility that the patient could be subject to a range of external factors that would influence his or her decision regarding end-of-life care or organ donation. Bioethical concerns specific to the medical staff related to the importance of voluntary participation and conscientious objection. There was also some concern regarding what information, if any, the recipient should receive regarding the source of the organs.

In addition, a number of practical considerations were raised. A number of these related to additional steps or modifications to the patient's end-of-life care to determine eligibility and to facilitate organ donation as well as medical considerations such as "no touch" time and the determination of death.

A range of safeguards or protections were suggested to address the various bioethical and practical considerations raised while ensuring public trust in the organ donation system. Many these suggestions or practices arise from non-Canadian jurisdictions, which often have different laws and practices governing WLSM, MAID and organ donation, as well as different social and cultural contexts. As such, it is important to pay attention to the greater context from which the safeguard arose. We also emphasize the need for a Canada specific approach to organ donation following WLSM and MAID. Thus, we believe that the key protections that may be relevant in the Canadian context include:

1. separation of decisions regarding WLSM or MAID and organ donation;
2. discussion of organ donation should occur only after the decision regarding WLSM/MAID has been made;
3. separation of teams: end-of-life care team, organ procurement team and organ transplant team;
4. coordination between these teams is needed to ensure that the patient receives the highest level of care and his or her wishes are respected to the extent possible.

Many of these safeguards already exist; they should be explicitly included in any policy around organ donation following WLSM or MAID. The task that lies ahead is striking the right balance between supporting those that want to be organ donors after a death from WLSM or MAID and protecting the public interest, particularly during these early days of MAID in Canada. While MAID itself remains controversial for both health care providers and the Canadian public, organ donation after death from the conscious competent patient can be provided in a legally and bioethically sound manner that that will honour the wishes of the individual choosing to end his or her life and potentially improve access to transplantation in Canada.

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Literature Search Terms

Concept	Keywords searched
5. Organ donation	6. organ donation 7. organ donor
8. Capacity	9. competent 10. capacity 11. capable
12. Underlying condition/request for WLSM or MAID	13. neuromuscular 14. neurodegenerative 15. ALS 16. sclerosis 17. assisted dying 18. assisted death

Overview of Themes & Issues

THEME	ISSUE	SOURCE
RATIONALE FOR AND AGAINST ORGAN DONATION AND MAID/WLSM		25 (486), 21 (31-32)
	For MAID – Similarities with WLSM	24 (16), 20 (630), 10 (1), 21 (30), 16 (3062)
	Increase organs available for donation	17 (584, 565), 25 (486), 18 (1191), 19 (517), 20 (632), 10 (5), 11 (32), 12 (247), 16 (3062), 13 (187-88), 14 (5), 16 (3061), 15 (39)
	Undermining public trust in O/D system	20 (633), 21 (32)
	Self-determination/autonomy	25 (487), 24 (17), 20 (631), 10 (3), 21 (31), 12 (249), 22 (586), 23 (1968-69), 13 (186), 13 (188-89, 192)
	Benefit to donor	24 (17), 13 (188, 192)
	Benefit to donor family	24 (17), 13 (188)
	Against – pressure on patient	10 (3), 21 (32), 12 (249)
	Cost effectiveness	20 (633), 10 (3), 21 (32), 12 (249)
	Public acceptance of assisted dying	20 (633)

ETHICAL CONSIDERATIONS		**20 (630-31)**
	Undue influence/coercion of donor	25 (488), 19 (517), 20 (634), 10 (3-4), 21 (32), 12 (249), 23 (1968-69), 13 (189)
	Motivation for donation	25 (489) 18 (1191), 24 (17), 10 (3), 23 (1968), 13 (189, 190)
	Impact on medical staff/health care professional	17 (563), 25 (488), 24 (17), 20 (632), 21 (31), 13 (186), 16 (3062)
	Recipient refusal	10 (4), 23 (1969), 13 (190), 15 (41)
	Conscientious objection of medical staff/health care professional	20 (633-34), 10 (4), 12 (250), 16 (3062), 23 (1970), 13 (186-87)
	Dignity of the donor	17 (565), 23 (1968)
	Consent	20 (632-33), 10 (3)
PRACTICAL CONSIDERATIONS		24 (17), 20 (633)
	Preparatory procedures (eligibility, pre-mortem interventions)	25 (488), 24 (17), 20 (630-32), 10 (3, 5), 12 (249), 16 (3062), 23 (1969-70), 13 (188, 190), 14 (6), 15 (40)
	Place of death (hospital vs. other)	25 (487), 25 (487), 10 (4), 12 (248), 16 (3062), 23 (1970), 13 (186-87)
	Impact on family (goodbye and grieving process)	25 (487), 24 (17), 10 (4), 23 (1970-71), 27 (74)
	Organ donation registry	25 (487), 10 (4)
	Determination of death	17 (582), 20 (632), 12 (248-49), 23 (1970), 13 (186, 191)
	Clinical/medical consideration	24 (17-19, 630), 20 (633), 12 (248-49), 16 (3061), 23 (1968), 23 (1970), 13 (186-87, 191), 27 (74), 15 (41-42, 44-45)
	Coordination of health care providers/procedures (end of life, procurement, transplant)	24 (19), 12 (248), 16 (3062), 23 (1969-70), 13 (187), 27 (75)
	Maastricht categories	18 (1190-92), 12 (248-49), 30 (3139, 3141), 15 (46)
	Impact on health care team	24 (17), 23 (1971)
	Avoids family veto	20 (632), 12 (249)
PROTECTIONS FOR POTENTIAL DONOR/PATIENT		28 (517), 12 (250), 21 (32)
	Separations of teams	24 (17), 25 (487), 10 (3-4), 22 (586), 16 (3062), 15 (39)
	Ensuring informed consent (includes capacity)	22 (586), 10 (2-3), 16 (3062), 23 (1968), 23 (1969), 14 (4-5), 27 (73-74)

	Separation of procedures	19 (517), 25 (488), 22 (586), 10 (4), 12 (249), 22 (586), 23 (1968), 23 (1969), 15 (44)
	Exclusion of minors	25 (487-88)
	Directed donation	10 (3), 23 (1968)
	Protection for physician/health care provider	25 (486-87), 21 (32)
THE "ASK"		21 (32)
	Universality	10 (4)
	Timing	25 (488), 19 (517), 20 (630), 13 (190), 27 (73), 15 (45)
	Who (MAID team/patient/OPO)	25 (488), 24 (17, 19), 10 (2), 21 (32), 23 (1968-69), 15 (39)
PUBLIC PERCEPTION		24 (18), 20 (633-34), 21 (32), 12 (249), 11 (44), 14 (3-4), 14 (3), 13 (186, 189)
	Mechanisms/policies to promote public trust in euthanasia and/or organ donation system (e.g. coroner, review committees)	17 (583), 19 (518), 25 (488), 10 (4-5), 12 (248), 16 (3062), 23 (1968, 1971)
ORGAN DONATION EUTHANASIA/DEAD DONOR RULE		25 (489), 20 (632), 11 (40-41), 10 (3), 28 (237, 239, 241-43), 23 (1968), 13 (191)
INTERNATIONAL EXPERIENCE		20 (633), 25 (486-87), 19 (515, 517)
	Take-up of organ donation and MAID	25 (486), 12 (249), 22 (585-86), 16 (3061-62), 23 (1967-68), 15 (29, 39, 44, 46)
	Satisfaction with procedure	
	Other	10 (2-3), 29 (134)

Appendix 5: Review of ALS Patients as Organ Donors

Should ALS patients be organ donors?

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What is ALS?

ALS is a neurodegenerative disease which causes progressive degeneration of the motor neurons in the motor cortex of the brain and the anterior horn cells of the spinal cord. The disease typically begins with focal neurogenic weakness and can progress to generalized weakness. Common initial presentations of the disease are difficulty speaking, difficulty swallowing, hand weakness, or foot weakness. Where ever the weakness begins, the patient will experience progressive weakness in that body region and the weakness will spread to involve other body regions.

The diagnosis of ALS is made typically by a neurologist who confirms the diagnosis after reviewing: the patient's story, examination findings, electrophysiology results, and other investigations. Typical ALS physical examination signs are weakness, muscle atrophy, fasciculations, hyperreflexia, spasticity, and other upper motor neuron findings. Unfortunately, there is no single laboratory or electrophysiological test that can confirm a diagnosis of ALS. As a consequence of not having a specific diagnostic test, a diagnosis of ALS requires an experienced clinician to be able to suspect ALS based on a typical history and examination findings, and the necessity of ruling out ALS mimics through appropriate investigations.

ALS has an incidence of 2-3 cases per 100,000 people and the disease can affect people of any age and any ethnicity. The mean age of onset of ALS is the late 50s or early 60s; but individuals may be diagnosed in their early 20s up until their late 80s. The disease is ultimately fatal with death usually secondary to respiratory failure. The average survival after symptom onset is 2-3 years, but the range of survival after symptom onset is 5 months to more than 50 years.

About 10% of patients with ALS have hereditary ALS, which means that their disease is inherited in an autosomal dominant or autosomal recessive manner. The majority of patients with ALS have "sporadic ALS" which means that their disease has not been caused by any genetic mutations known to cause ALS and there is no evidence of other family members with ALS. The cause of sporadic ALS has not been definitively determined. Science has identified several factors that may increase the risk of a patient developing ALS on a cellular level such as protein aggregation, oxidative stress, mitochondrial dysfunction, and inflammation. As for environmental factors that may increase the risk of sporadic ALS, only weak associations have been found.

Although classically described as a predominately motor disease, ALS is now recognized to cause frontal executive, social cognition or behavioural impairments in a proportion of patients. On formal neuropsychological testing, 50% of patients with ALS will have frontotemporal cognitive impairments or behavioural impairments. Up to 40% of these patients with ALS will have sufficient cognitive or behavioural impairment to cause functional impairment and are classified as having frontotemporal dementia (FTD).

There are a few pharmacological treatments which have demonstrated modest benefit in slowing the progression of ALS. Riluzole, a glutamate antagonist, is the oldest ALS treatment and is approved in all regions of Canada. In Canada, there are no other approved medications for ALS. On May 5th, 2017, the FDA approved edaravone which is an intravenous free radical scavenger for the treatment of ALS. The European Medicines Agency (EMA) has recently received an application for masitinib, an oral mast cell inhibitor, for the treatment of ALS. We expect that the manufacturers of masitinib and edaravone will

be pursuing Health Canada approval for these two medications. However, both of these two medications have only demonstrated modest slowing of the disease progression.

After diagnosis, management of ALS patients focuses on symptom management, motor function support, nutrition interventions and respiratory support. As mentioned above, patients with ALS will eventually die of respiratory failure. However, there are a number of respiratory interventions that can prolong survival in ALS. Specifically, non-invasive ventilation (NIV), invasive ventilation and mechanical in/exsufflators can support patients with significant respiratory muscle weakness. Some patients with ALS start using non-invasive ventilation and slowly progress to using non-invasive ventilation for 24hours a day.

Rationale for exploring organ donation from patients with ALS

There is no disputing the fact that there is a shortage of organs for organ transplantation. Identification of new sources of organs for transplantation is important and patients dying of ALS could potentially be a new source of organs.

Avenues of potential organ donation from ALS patients

ALS is not known to cause any organ impairments outside of the brain and spinal cord. Although there is respiratory muscle weakness in ALS, the lung parenchyma should otherwise be normal. Patients with ALS often have interest in donation of their organs. 40-year-old woman with ALS in San Francisco decided to proceed with DCD and made this statement prior to her death: "I am glad that in spite of my disease, there is still something I can do to help others in a significant way. ALS is preventing me from accomplishing what I wanted to do in my life, but hopefully, my donation will give others a chance to live out their dreams". (Toossi et al in Ann Neurol 2012).

There are 3 ways that an ALS patient could potentially offer to donate their organs:

1. Donation through DCD after discontinuation of invasive ventilation
2. Donation through DCD after discontinuation of continuous non-invasive ventilation (NIV) support.
3. Donation after Medical Assistance in Dying (MAID).

Patients with ALS often ask if they are organ donation candidates in ALS clinics, without prompting by the ALS clinic staff. Patients are often willing to have an open discussion about the topic of organ donation.

Evidence for or against the transmissibility of ALS

In order to classify and understand the evidence regarding the transmissibility of ALS, we have performed an extensive librarian assisted literature search of Medline and EMBASE. The literature search used synonyms for ALS and combined that with standard search terms for organ transplantation or transmissibility/transmissible/transmission. Papers were limited to English or French. The search was meant to be comprehensive. There were 4003 abstracts returned and 55 of these abstracts were selected to be of potential relevance. Those papers were pulled for further review. The evidence extracted from the papers were divided into 3 categories: cell culture, animal and human data.

ALS research currently uses models of familial ALS to study the disease. Unfortunately, there are no great models of sporadic ALS that have been identified. The most common model used in animal research in ALS is the mSOD1 mouse. Mutations in super oxide dismutase 1 (SOD1) were the first mutations discovered that cause familial ALS (1993). As a consequence, the SOD1 mouse models are often the most well developed. More recently, other genetic causes of familial ALS have been found such as TDP-43 (2008) and FUS (2009) mutations. In 2011, expanded repeats in the c9orf72 gene, were identified as the most common cause of familial ALS (35% of familial ALS). The finding of new genetic causes of ALS has allowed for development of new cellular and animal models of ALS.

Evidence of ALS transmission in cell cultures

Since protein misfolding and protein aggregation are felt to be hallmarks of ALS pathology, most of the studies of transmissibility through cell cultures look at the potential for cell to cell transmissibility of protein misfolding or protein aggregation. Authors of the papers often refer to the potential for prion-like capacity of ALS because of the protein inducing misfolding and/or aggregation seen in ALS models. In order to clarify infectivity concepts, it is worth elucidating the definition of a prion and prion-like condition. A prion is an infectious agent composed entirely of protein material. Misfolding of the prion protein, PrP, triggers other proteins to also misfold and cause disease. A prion-like disorder can induce protein misfolding and cell to cell transmission, but that there is no evidence (yet) of transmissibility through blood transmission (Cushman 2013).

Several papers addressed the possibility of mutated SOD1 proteins to induce misfolding in other mutant SOD1 proteins and also in wildtype SOD1 proteins. These papers also look at that fact that SOD1 misfolding can be transmitted through adjacent cells, likely via exosomal secretion of misfolded protein (Ayers 2014, Fernando 2014).

Almost all autopsy specimens of patients dying of ALS demonstrate TDP43 inclusions. The main exceptions to TDP43 inclusions are those patients with SOD1 mutations and FUS mutations. As a consequence, TDP43 aggregates are often studied in ALS research. A number of papers have looked at the potential of cell to cell transmissibility of TDP43 misfolding and aggregation. A portion of the TDP43 (c terminus) has a sequence similar to that of prion protein. Furthermore, the extent of pathology is proportional to the amount of aggregate present (Guo 2011). TDP43 aggregates can act as a seed for further aggregation and induce cell death (Nonaka 2013). TDP 43 can be transmitted within and between cells. Exosomal transport is one of the hypotheses for the mechanism of transmission of protein aggregates between cells (Fevrier 2005), (Nonaka 2013). There exists both horizontal (adjacent cells) and vertical (synaptic transmission). While exosomes have been found in CSF (Street 2012), we have not found evidence for the ability of lysosomes to cross blood brain barrier.

The CSF from patients with ALS can serve as the seed to propagate the disease. TDP 43 aggregation can be induced in vitro by treating a human glioma cell line with CSF from patients with ALS- FTD (Ding et al 2016). However, CSF from ALS patients without FTD did not induce TDP43 aggregates. The two patient groups were significantly different in age, with the ALS/FTD group being older than the ALS group and this difference may have been pathologically significant. Interpretation of this result is challenging. Was the induction in TDP43 aggregation due to an over representation of familial variants in the ALS-FTD group? Or was there age associated factors that contributed most to the aggregation?

There is also some early evidence of potential cell to cell transmission in C9orf72 associated pathology. Chang et al (2016) demonstrated cell to cell transmission of C9orf72 repeat GA fibrils in a neuroblastoma line. Westergard et al in Cell 2016 found evidence of cell to cell spreading of dipeptide repeats in induced pluripotent stem cells from C9orf72 patients (DPRs are the protein product of the hexanucleotide repeat seen in C9orf72 repeat expansions). It is unclear if transmission of DPRs is sufficient to induce development of typical ALS pathology.

Evidence of ALS transmission in animal models

Fraser et al did an experiment in 1996 whereby they inoculated mice with brain and spinal cord homogenates from patients who had died of ALS. The inoculation was done both intracranially and intraperitoneally in separate mice and the mice were observed for 600-800 days. None of the mice developed ALS. However, one has to wonder whether the transmission was prevented due to the species barrier and whether the mice were observed long enough.

Ayers et al (2014) performed inoculation of mSOD1 spinal cord homogenates into the spine of neonatal mice and found that only mice that were genetically vulnerable developed pathology. Specifically, mice that were carriers (heterozygotes) of a SOD1 mutation that only causes disease in a homozygote, developed ALS. However, the wildtype mice that did not carry any mutations in the SOD1 gene did not develop ALS. This is an important finding that might suggest that only genetically vulnerable animals or potentially patients may develop ALS when exposed to tissue from an animal or human with ALS.

A Canadian experiment connecting a mouse with ALS secondary to mSOD1 to a mouse without ALS through an artificial blood connection via anastomosis of larger arteries in the mice did not cause ALS in the normal mouse, indicating that there was no evidence of blood transmission (personal communication with Dr. Fabio Rossi).

Evidence of ALS transmission in humans

The National Institutes of Health (NIH) in the US have long history of collection of autopsy specimens of neurodegenerative diseases and cases of CJD. Decades ago, brain autopsy tissue was inoculated into monkeys to determine if a condition was transmissible. In 1983, Salazar and colleagues collected a series of cases referred to the NIH with amyotrophy and dementia at the time of death. Presumably several of these cases had ALS-FTD and several of the cases may also have had CJD. They looked at these cases to determine if any of the cases demonstrated transmission to monkeys through intracerebral inoculation. 2 cases out of 25 showed demonstrated transmission. The first case that demonstrated transmission was likely a case of a patient with a longstanding hereditary neuropathy which caused the muscle wasting, followed by typical CJD. The second case was rapidly progressive dementia and amyotrophy with death 6 months after the onset of symptoms. Due to the rapidly progressive nature of this patient's disease, it is much more likely that his disease was due to CJD although it is theoretically possible it was extremely rapidly progressive ALS. 23 cases of dementia with amyotrophy (which in retrospect were likely mostly ALS-FTD) did not demonstrate any transmission in the monkeys after 3-12 years of observation.

However, Connolly wrote a letter to the Journal of Neurology, Neurosurgery and Psychiatry in 1988 reporting a case of a monkey inoculated with brain tissue from a human dying of "the amyotrophic form of CJD" which was originally reported as having no evidence of transmission in the 1983 Salazar publication mentioned in the preceding paragraph. This monkey was inoculated intracerebrally on May 17, 1971 with autopsy brain tissue from a patient who died with dementia and amyotrophy. The monkey died on August 10, 1984 and the necropsy demonstrated mild spongiform changes in the cortex which the authors reported was diagnostic of CJD. In retrospect, it is possible that the findings were not specific for CJD because autopsy findings of patients with ALS-FTD also show spongiform changes in the cortex. Unfortunately, without more clinical data on the human patient, it is very difficult to know if they died of ALS-FTD or CJD, and therefore which disease was transmissible.

Although it is theoretically possible that ALS (or at least ALS-FTD) can be transmitted via direct brain inoculation, is there any evidence that ALS transmission can cross the blood brain barrier? The blood brain barrier protects that brain and spinal cord from bacteria and from several pharmaceutical agents. As a consequence of the tight junctions in the blood brain barrier, some medications have to be administered directly into the cerebral spinal fluid in order to access the brain. Edgrin and colleagues (Ann Internal Med 2016) looked at the risks of development of neurodegenerative disease from a blood transfusion through analysis of a Sweden and Denmark transfusion database. They found no increased risk identified for ALS (or other neurodegenerative diseases), despite 2.9% receiving a transfusion from an individual who was eventually diagnosed with a neurodegenerative disease. However, the number of recipients exposed to blood from an individual with ALS was low.

Huot et al (Transplant international 2013) looked at a French transplant database and assessed recipient health of those receiving organs from patients with rare diseases. From January 2007 to December 2012, 388 donors were found with rare diseases (0.4% of the total number of donors). 40% of those with rare diseases had neurodegenerative diseases including ALS, Multiple Sclerosis, and chorea. Recipients were followed up to 5 years and no obvious transmission occurred. Unfortunately, only abstract data is available and so it is unclear how many patients were transplanted with organs from patients with ALS.

It is also important to review the possible transmission of ALS through human pituitary extracts. Irwin and colleagues (2013) looked at a database of human growth hormone recipients from who had received pituitary extracts subcutaneously from cadaveric pituitary glands. The database included 6190 recipients of human cadaveric pituitary extracts for growth hormone treatment and 796 of the recipients were deceased. The authors discovered 2 cases of patients who had died of ALS and a literature search revealed one additional case of death secondary to ALS in a cadaveric pituitary growth hormone recipient. In the database, both ALS deaths involved patients in their 30s, and the other published case was an individual who was 18 years of age. Each of the 3 cases developed ALS multiple years after administration of the pituitary extract. One case was 15-24 years after administration of hormones, another case was 13-19 years after hormones, and the third case was 10 years after hormone administration. One case in the database had no autopsy and chart review not possible to confirm that the cause of death was definitely ALS and not another disease. One case did have a chart review available and the reviewers felt that the story was consistent with ALS. That individual did have an autopsy, but that autopsy was prior to modern ALS pathology labelling techniques (such as TDP43 labelling). These three cases are concerning for the potential for ALS transmissibility. However, we do not know if the cadaveric pituitary tissue was from an individual with ALS which would definitively increase the likelihood that ALS is transmissible after at least ten years. It is also possible that the illnesses of the recipients that necessitated the administration of growth hormone or the medications that they received for their condition may have been the trigger for their ALS.

Transplantation of ALS organs has already occurred

Toossi and colleagues in 2012 reported that 12 ALS patients in the US had proceeded with DCD in the US prior to 2011. Smith and colleagues report 2 patients with ALS that elected to donate organs after DCD. It is unclear if the two patients that Smith reports are part of the twelve-patient cohort of Toossi et al, but the authors on the papers are different. A few ALS patients in Ontario have also donated their organs. There have been no subsequent published reports of transmission of ALS in any of the recipients of these organs from ALS patients.

Opinions of ALS transmissibility in the Canadian ALS research community

The literature review information contained in this report was presented to the Canadian ALS research community at the ALS Canada Annual Research Forum on April 30, 2017. The Canadian ALS research community was subsequently asked several questions via Survey Monkey about their opinions about the possibility of ALS transmission through organ transplantation. They were also asked questions about if transplant recipients should be informed they are receiving an organ from an ALS patient and how these recipients should be followed. 40 individuals completed the survey. 11 of the respondents were ALS Clinicians, 14 were basic science ALS researchers, 4 were Post-doctoral students, 4 were PhD students, 4 were masters students, and 3 selected “other”. When asked “Is ALS transmissible through organ transplantation”, 0% responded “yes”, 7.5% responded “no”, 55% responded “unlikely”, and 37.5% responded “uncertain”.

When asked “Is ALS transmissibility risk different for sporadic vs hereditary ALS?” respondents said: “Yes” (12.8%), “No” (28.2%), “Unlikely” (18%) and “Uncertain” (41%). They were also asked “Are

certain familial ALS mutations more likely to be transmissible?". 21% responded "Yes", 23.7% responded "No" and 55.3% were uncertain. Those respondents who included comments on this question mentioned SOD1 mutations, TDP43 mutations and C9orf72 expansions as being the mutations potentially at risk of causing transmission.

When asked "Should we transplant organs from ALS patients?", 53.9% of respondents said "Yes", 12.8% said "No", and 33.3% said "Uncertain". 52.5% of respondents indicated that they felt recipients of ALS organs should be informed that their organ came from a patient with ALS. 15% said that organ recipients should not be informed to protect the confidentiality of the donor. 32.5% were unsure if recipients should or should not be informed of the fact that their organ can from an ALS patient. The majority of respondents did suggest that transplant recipients of ALS organs should be monitored for the development of ALS and that reporting of ALS in transplant recipients should occur.

Summary Statements

1. It cannot be definitively determined if ALS is or is not transmissible.
2. It is likely that intracerebral or intraspinal transmission of ALS can occur. The blood brain barrier may protect against ALS transmission from solid organ transplantation.
3. Organ recipients with genetic vulnerability for ALS (that is patients carrying ALS genetic mutations) may be more likely to develop ALS through transmission of protein misfolding. In other words, potential recipients with a first degree relative with ALS may be at higher risk of developing ALS from a transplanted organ from an ALS patient.
4. If ALS is transmissible through organ transplantation, it will likely take more than ten years to develop. This estimate of ten years is taken from the human pituitary growth hormone database publication.
5. Recipients need to be given the choice as to whether they would like to receive an organ from an ALS patient and they need to be informed that we are unsure if ALS is transmissible.
6. Recipients of organs from ALS patients need to be followed closely for development of ALS for the duration of their lives. ALS transmission may not occur for over 15 years and so there should be long term follow-up of these patients.
7. Any transplant patient developing ALS or other neurodegenerative disease needs to have their status reported to their provincial transplant agency. This includes patients who did not receive an organ from a patient with a known neurodegenerative disease. Understanding the baseline risk of ALS in any solid organ recipient will be very important when assessing the correlation of development of ALS with the donated organ.

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Appendix 6: Conscientious Objection – A scoping review

Conscientious Objection – Dr. Daniel Buchman, Ms. Vanessa Gruben

INTRODUCTION

The concept of conscientious objection (CO) has roots in military contexts. Conscientious objectors refuse to participate in war because, for example, they find the taking of another human life as intrinsically wrong (1). Prior to the 1970s—and the 1973 Roe v. Wade United States Supreme Court decision that struck down abortion laws—CO was rarely mentioned in the health care literature but has been well established since that time (2, 3). Paradigmatic examples of CO in health care pertain to issues such as reproductive health (e.g., providing contraception, abortion, in vitro fertilization), and medical assistance in dying (MAID) (1). In these scenarios, the health care professional encounters tension between her or his personal and professional moral commitments (4-6). Medical assistance in dying, for example, might conflict with the clinician's core values as a person and/or the values of the clinician's profession (e.g. minimizing suffering and preserving the sanctity of human life) (1, 4, 7). The Canadian law on MAID states that "everyone has freedom of conscience and religion under section 2 of the Canadian Charter of Rights and Freedoms" and "nothing…compels an individual to provide or assist in providing medical assistance in dying" (8). It is not well understood how CO applies to emerging areas impacting MAID, such as organ donation. The purpose of this scoping review is to determine how the literature defines CO related to MAID and organ donation and to describe the scope and limits of its theory and practice in this context.

METHODS

Scoping Review

We used Arksey and O'Malley's framework to guide the scoping review (9). First, we established the scoping review purpose and research question. Second, we developed search criteria in consultation with a library information specialist, and then we identified the appropriate studies for inclusion based on our search criteria. Third, we engaged in an iterative process of study selection which includes searching the literature, refining the search criteria, and reviewing the articles for inclusion. Fourth, we charted the data in an iterative process that involves cycling back and forth between the data and the chart and ensuring that the extracted studies aligned with our research question. Fifth, we collated, summarized, and reported the data extracted from the articles using a qualitative thematic analysis (10). In this paper, we will use MAID interchangeably with terms such as (active) euthanasia, assisted suicide, physician assisted suicide, and physician assisted death. We acknowledge that there are practical differences between the acts of assisted suicide (e.g. patient self-administration) and active euthanasia (e.g. physician or nurse practitioner administration).

Data Collection

We searched Ovid Medline, Ovid Medline epub/inprocess, Embase, Cochrane CENTRAL, PsycINFO, CINAHL, and PubMed for non-Medline records. On January 11, 2017, we searched Philosopher's Index (UofT). We manually checked the reference list and citations selected for inclusion for further articles in our review.

Inclusion and Exclusion

Criteria Articles were included if they were English language; directly discussed (i.e., devoted at least one paragraph) health care provider (e.g., nurse, surgeon, pharmacist, physician) conscientious objection and active euthanasia (or physician assisted suicide, MAID, or a relevant synonym) and/or organ donation; published up to January 11, 2017. Articles were excluded if they were an editorial, commentary, letter to the editor, book or book chapter, or did not directly discuss CO. If CO was directly

discussed but was not about MAID and/or organ donation (e.g. the article discussed abortion), the article was excluded.

Data Analysis

Data were analyzed using a thematic analysis approach. Thematic analysis is a method for identifying, analyzing, and reporting themes in rich detail within qualitative data (8). Articles were reviewed and analyzed by DZB and VG. The data were extracted from the articles and placed in a spreadsheet as part of the charting process.

RESULTS

Our search yielded N=1,208 citations. Our manual search yielded an additional n=6 relevant articles. A total of n=48 articles were included in the full-text analysis. Included articles were published between 1985 and 2017. The literature included perspectives from the United States (n=19), Canada (n=6), Britain (n=6), the Netherlands (n=6), Belgium (n=3), the Netherlands (n=1), and Ireland, Japan, New Zealand, and Switzerland (n=1, respectively). Five major themes were identified: (1) Lack of Consensus on Definitions, Scope, and Limits; (2) The Necessity, Boundaries, and Limits of a Duty to Refer; (3) Participation and Cooperation Among Interprofessional Health care Providers; (4) Tensions Between Conscious-Based Refusals and Job Security; and (5) Potential Harms to the Donor, Transplant Candidate, and Public Health.

1. Lack of Consensus on Definitions, Scope, and Limits

Most papers did not provide a definition of CO but invoked the term or discussed objections related to matters of conscience. As we describe in Theme 4 below, none of the articles we reviewed on organ donation after MAID that mentioned conscientious objection (n=3) provided a definition. Justification for accommodating CO in the context of MAID is based on the values of professional autonomy, liberty, and moral integrity (6, 11). Further arguments claim that MAID is incongruent with the goals of medicine—to promote health and prevent disease—so CO can be defended on grounds of professional values (3, 12). Childress distinguished CO from civil disobedience. Childress states that CO is "…public, nonviolent, and submissive violations of law based on personal-moral, often religious, convictions and intended primarily to witness those principles or values" (13). In the literature, health care-specific definitions ranged from broad, such as providers should be able to object on "grounds of conscience" (14), to specific, "allowing medical professionals not to participate directly in practices they view as morally wrong" (1). Additional definitions attempted to put boundaries around the scope of CO by situating the CO within the realm of the health care provider's expected duties and obligations: "[t]here can be a conscientious objection only to a certain act, in this case euthanasia. It is impossible to hold a conscientious objection to caring for patients in general…"(15). While most definitions of CO emphasize and focus on the health care provider's interests, other papers extended the definition to include considerations of potential harms to patients: "…the right to conscientiously object to any procedure that they deem as morally illicit or that, in their opinion, could harm the patient" (16).

Perspectives on the bioethical permissibility of CO for MAID were diverse. Most papers supported CO (4, 7, 16, 17), while others posited that physicians have no moral claim to CO in liberal Western democracies; physicians' private moral views on MAID should not be considered more important than their patients' needs (18, 19). For example, "a doctors' conscience has little place in the delivery of modern medical care" (20). Indeed, some health care providers may feel obligated to not abandon their patient who is choosing MAID even though the health care provider may object to the practice (15, 21). Two surveys of U.S. physicians found that physicians who believe they are never obligated to do what they believe is morally wrong had higher religiosity and greater support for objections to medically-assisted suicide (22, 23). Indeed, authors arguing in favour of CO tend to come from religious perspectives which argue that MAID is impermissible (24-27).

Religious perspectives are grounded in the view of the sanctity of human life and that MAID devalues that sanctity. For example, "life is a precious gift from God…Life is being remorselessly devalued in our secular society…To legalize euthanasia would be one more major devaluation" (26). Some sources stated that health care providers should have a right to conscientiously object to interventions they deem morally problematic such as MAID (16, 27, 28). This is reflected in "conscience clause" legislation in several countries, including several American states (7), New Zealand (29), and Britain (30). Conscience clauses, or "health care refusal measures" (31), have been instituted to legally protect conscientiously objecting health care providers and may permit some institutions to refuse to perform certain procedures such as MAID, although this is a matter of debate (32).

2. The Necessity, Boundaries, and Limits of a Duty to Refer

It is uncontroversial that physicians have duties and obligations toward their patients, however the extent of these differed in scope (4). This was reflected in a tension in the literature between proponents and opponents of a duty to refer (also called effective referral, transfer, facilitation, or reasonable accommodation; there are moral differences between these terms, but we do not address them here). Proponents suggested that CO should not delay, impede, or block patient access to MAID. If physicians have a legal and moral right to conscientiously object, this should not be a limited right because qualifying patients have a legal right to MAID. This means that objecting providers have a legal and ethical obligation to refer the patient to a non-objecting health care provider without it negatively impacting the patient's care or provide the patient information about other non-objecting agencies (30, 33-35).

There was no consensus in the literature about whether religious-based institutions who object to MAID but receive public funds must facilitate a timely transfer of care that is not overly burdensome for the patient (32). 5 The concept of effective referral was not necessarily considered a defensible compromise in the literature. Opponents considered facilitating an effective referral to be complicit in an act that the objector considers morally wrong; some questioned whether facilitation makes the agent morally responsible (1, 32, 36). Other authors noted that the legal right to freedom of conscience entails that legislation cannot impose a duty to refer (32, 37).

3. Participation and Cooperation among Interprofessional Health Care Providers

The nursing literature, namely in the United States, has historically suggested that nurses should abstain from participating in MAID (11, 25, 38). Some argue that professional position statements that support nurses participating in MAID are misguided due to confusion about the meaning of conscience, misuses of professional codes of ethics, and failure to recognize the primacy of human dignity (25). Conscientious objection was also invoked for nurses who have strong conscience commitments to providing MAID for their patients: an act of CO was defined as participating directly in a MAID and thus in violation of the professional code of nursing (38). The terms "participation" and "cooperation" are points of controversy in the MAID literature, especially for health care professionals such as nurses and pharmacists (39). These groups may not always directly intervene to cause a patient's death (e.g. they do not typically perform active euthanasia) but perceive that they could be morally implicated by assisting physicians who provide euthanasia by performing tasks such as helping to plan the euthanasia or filling a syringe (11, 39). Questions arise about the scope and limits of participation, cooperation, and moral responsibility (39). This includes questions as to whether filling prescriptions for MAID is morally equivalent to directly participating in the MAID procedure (40).

4. Tension between Conscience-Based Refusals and Job Security

The literature suggests that some non-physician health care professionals are concerned that they would not be permitted to follow their conscience (i.e., object to an act) and must follow through with

an act they find personally morally objectionable. If they refused to participate in MAID, they were worried this may lead to termination of employment: "…will I be so afraid of being fired that I'll give in even though I ethically oppose what's being done for a patient" (41)? Some pharmacists may encounter similar dilemmas between fulfilling their duty to provide medically and legally appropriate medications and becoming directly involved in a practice (i.e., MAID) that they find morally problematic (17, 40).

5. Potential Harms to the Donor and the Transplant Candidate

Six articles discussed organ donation after MAID. None of the articles provided a definition of CO. Three of the articles mentioned CO (42-44) while the others did not (45-47). One article 6 from the Netherlands implied the concept of CO and stated, "[f]ollowing Eurotransplant regulations, recipients and their physicians have the opportunity to refuse certain types of donor organs when a patient is placed on the waitlist…[this] should also include donor organs from donors after euthanasia" (46). However, the paper did not state whether this is a conscience-based refusal and did not go into any further detail about the limits and scope of this refusal. Conscientious objection is sometimes discussed in the context of donation after circulatory death (DCD), given that there is a historical debate as to whether DCD violates the dead donor rule, which is that a) organs can only be retrieved from donors who are dead and b) retrieval of organs must not be the cause of death (48, 49). Given the controversy over MAID, some health care providers may wish to extend a conscience claim to the retrieval and transplantation of organs from donors who died from MAID (42, 43). Conscientiously objecting to using organs from patients who accessed assisted death might be ethically problematic because "doing so would contribute to avoidable patient deaths" (42, 43). There are inconsistencies in refusing to retrieve organs from people who accessed MAID, as people who die by controversial means (e.g. suicide) are sources of organs in many jurisdictions (44). Some authors suggest that the scope of CO can be extended to physicians who refuse to retrieve organs from someone who died by MAID, but only if a referral is made to a non-objecting surgeon (33, 43). An effective referral (please see Theme 3) within the same transplant centre is necessary so that the donor's wishes are respected and use of the organ is not lost (33). However, an effective referral to another hospital to retrieve the organs is considered ethically untenable (as well as practically challenging) because of the financial burdens this referral places, the emotional strain on families, and that the transfer delays the death, which may harm transplant candidates on the waiting list (33, 42).

Summary of Findings from the Scoping Review

Summary of Key Themes

Theme Summary

1. Lack of Consensus on Definitions, Scope, and Limits
   - The literature tends to support the notion of CO for health care providers, but there is no consensus on its scope or limits
2. The Necessity, Boundaries, and Limits of a Duty to Refer
   - The literature was divided between the position that a conscientiously objecting health care provider should refer the patient to a willing and available provider and the position that any degree of referral as being complicit in a morally wrong act
3. Participation and Cooperation Among Interprofessional Health Care Providers
   - Terms such as participation and cooperation are points of controversy in the MAID literature (7)
   - Some health care providers, such as nurses and pharmacists, may perceive themselves to be morally implicated in MAID even if they do not directly provide the MAID intervention
4. Tensions between Conscience-Based Refusals and Job Security
   - Some health care providers may perceive that they have no power to CO to an act they find morally objectionable without risks to their employment
5. Potential Harms to the Donor and the Transplant Candidate

- Scarce literature
- Objecting to using organs from MAID donors may lead to patient deaths
- Refusal does not respect patient's wish to donate.

DISCUSSION

We found that while CO is a well-established concept in health care, it is variably defined in the literature on MAID. Articles on CO in the context of organ donation after MAID are extremely limited. Ethical issues common in organ donation and transplant ethics such as conflicts of interest, coercion or undue influence, and decision-making capacity did not appear in our results. All citizens of Canada including Canadian health care providers enjoy the freedom of conscience and religion under the Charter. Given the controversy over MAID, some individual health care providers, transplant programs, or hospitals, may object to using organs from donors who died from MAID. Based on our analysis of the literature, we suggest that these are objections on practical grounds, not grounds of conscience; the person may have a moral or religious objection to MAID, not to the retrieval or the transplantation of organs which is part of the person's normal scope of practice. If individual health care providers, transplant programs, or hospitals, object to using organs from donors who died from MAID, this may delay, impede, or potentially prevent the use of organs for transplant and lives may be lost. There are concerns in the literature that without proper clarity on the definition and scope of CO, exemptions that are incorrectly claimed to be conscience-based will become increasingly common (37). This may lead to significant burdens on patients, staff, and institutions (33, 37). Objections to using organs based on how the person died may be inconsistent across health care providers and institutions, thus introducing additional inequities into the organ donation and transplantation system (20). It is possible that some health care providers who refuse to retrieve or transplant organs from MAID donors may be concerned about "cooperation" with MAID, as described in Theme 3. However, their participation does not extend to the MAID act because the person has already been declared dead and the objecting provider had no role in the events leading up to or even causing the death. At this stage, the objecting provider would be objecting to performing acts that are central to his or her role (8). The literature does not support the claims of health care providers to refuse to use organs retrieved from a patient who died from MAID. Patients who wish to donate their organs after MAID also have interests and values that are due consideration, and may not be respected by a refusal, and these include dignity, autonomy, and well-being (3, 43).

LIMITATIONS

Our review did not include an analysis of policies from professional colleges, as these organizations typically provide guidance for their membership on how they should approach the issue of conscientious objection. Only English-language articles were included in the review. It is possible that non-English articles published from the Netherlands and Belgium, where organ donation after euthanasia is practiced, was not captured by our search. There were an additional 10 articles that were captured by our initial search but were not evaluated at the full-text stage because they could not be located online or in hard copy or through inter-library loan.

CONCLUSIONS

The purpose of this scoping review was to determine how the literature defines CO related to MAID and organ donation and to describe the scope and limits of its theory and practice in this context. While the term CO is firmly situated in discourses on MAID, it has received scant attention in emerging areas such as organ donation. Future research can explore the intuitions underpinning and reasons why organ

retrieval teams as well as transplant surgeons and staff may raise objections to using organs from MAID donors when these professionals may not be involved in the MAID itself.

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Appendix 7: Workshop Agenda

Canadian Blood Services
Société canadienne du sang

In collaboration with:

CCCS | Canadian Society of Transplantation | Canadian Association of Critical Care Nurses

Organ and Tissue Donation in the Conscious Competent Patient

Workshop Agenda for Monday May 15, 2017 (Day 1)

Sheraton Gateway Hotel (Terminal 3, 3000 Toronto Pearson International Airport) – Alpine Room

8:00 – 8:30	**Breakfast**	
	Presentation	**Presenter(s)**
8:30 – 8:50	Welcome from Canadian Blood Services	Dr. Sam Shemie Kimberly Young
8:50 – 9:05	Around the Room	Individual Introductions
9:05 – 9:15	Process and Meeting Design	Dr. Sam Shemie
Setting the Stage		
	Presentation	**Presenter(s)**
9:15 – 9:35	Challenge Address	Dr. Michael Sharpe
9:35 – 9:55	Evolution, Demographics, Practical and Procedural Aspects of MAID in Canada	Dr. James Downar
9:55 – 10:25	Organ Donation after Euthanasia in Belgium	Dr. Dirk Ysebaert
10:25 – 10:40	Q&A	
10:40 – 11:00	**Break**	
11:00 – 12:00	**Group Participation Questions**	
12:00 – 12:45	**Lunch**	
Expectations of Patients, Families and the Public		
	Presentation	**Presenter(s)**
12:45 – 13:20	Patient Perspectives	Dr. Shelly Sarwal Sandra Martin
13:20 – 13:30	Q&A	
13:30 – 13:50	Preliminary Ontario Experience Commentary from Quebec	Dr. Andrew Healey Dr. Jean-François Lizé
13:50 – 14:45	**Group Participation Questions**	
14:45 – 15:00	**Break**	
Legal and Ethical Considerations		
	Presentation	**Presenter(s)**
15:00 – 15:20	Legal/Ethical Review	Vanessa Gruben
15:20 – 15:35	Views from Quebec	Marie-Noëlle Saint-Pierre
15:35 – 15:50	Legal/Ethical Panel Q&A	Daniel Buchman Dr. Marie-Chantal Fortin Vanessa Gruben Marie-Noëlle Saint-Pierre
15:50 – 17 :00	**Group Participation Questions**	

17:00 – 19:00 Reception in Alpine Foyer

Canadian Blood Services
Société canadienne du sang

In collaboration with:

CCCS | Canadian Society of Transplantation | Canadian Association of Critical Care Nurses

Organ and Tissue Donation in the Conscious Competent Patient

Meeting Agenda for Tuesday May 16, 2017 (Day 2)

Sheraton Gateway Hotel (Terminal 3, 3000 Toronto Pearson International Airport) – Alpine Room

7:30 – 8:00	**Breakfast**	
	Presentation	**Presenter(s)**
8:00 – 8:15	Recap of Day 1 and Introduction to Day 2	Dr. Sam Shemie Dr. Michael Sharpe
8:15 – 9:45	**Group Participation Questions**	
9:45 – 10:00	**Break**	
Eligibility to Donate		
	Presentation	**Presenter(s)**
10:00 – 10:25	End Stage Neurological Conditions and Organ Donation Implications	Dr. Christen Shoesmith
10:25 – 10:30	Q&A	
10:30 – 12:00	**Group Participation Questions**	
12:00 – 12:45	**Lunch**	
Quality and Accountability		
	Presentation	**Presenter(s)**
12:45 – 13:05	Coroners Perspective on MAID and Organ Donation	Dr. Dirk Huyer
13:05 – 14:15	**Group Participation Questions**	
14:15 – 14:50	Reflections: – Research Feedback – Proposed Public Communication Strategy	
14:50 – 15:00	Closing Comments	

Appendix 8: Fact Sheets and Workshop Questions

Challenges Questions & Fact Sheets

Questions:

1. Discuss the advantages and disadvantages of routine requests (approach all patients) versus responding only to patient-initiated requests for OTD?
    a. Which approach do you favor and why?
    b. Should there be any differences in approach between patients who consent to MAID and patients who consent to WLSM?
    c. In what way, if any, would previously registering one's intent to donate (organ donor registry, driver's license, health card) influence your preference for routine requests vs. patient-initiated requests for OTD?

IPSOS Reid Canadian Public Survey Sept 2016, n=1006

- Ninety-two percent of Canadians approve of people donating their organs at the time of their death.
- Support for the idea that a patient who is conscious and competent should be eligible to donate their organs if they decide to withdraw life-sustaining treatment (87%) or receive medical aid in dying (80%) remains high, however support is significantly lower than the approval recorded for organ donation in general (92%).
- Older respondents and females were more likely to approve or support organ donation under these circumstances.
- A significantly higher proportion oppose the idea of a patient who receives medical aid in dying donating their organs (12%, compared to 6% who oppose donation after withdrawal of life-sustaining treatment and 4% who oppose organ donation in general).
- Concerns of those who oppose organ donation under these circumstances include the risk of the donors' illness being transmitted to the recipient of the organ (48%), the possibility of vulnerable persons feeling pressured to withdraw life-sustaining treatment or choose medical aid in dying sooner than they may have otherwise (46%), or vulnerable persons feeling pressured to donate their organs (43%).
- Eight in ten agree that physicians or other qualified medical practitioners should be required to discuss organ donation with all adult patients regardless of illness/condition or end-of life care decision.
- Seventy-five percent of respondents think the decision of who should or should not donate their organs should take into consider both scientific evidence and the concerns of donation recipients.
- The majority agree (83%) that the decision to donate organs should be reconfirmed prior to end-of-life care being administered, however fewer agree (53%) that organ donation should only be discussed AFTER a decision regarding withdrawal of life-sustaining treatment or receiving medical aid in dying is made.
- Despite high approval for organ donation overall, as well as high support for donation after end-of-life care is administered, a quarter are undecided about whether they would be willing to accept an organ transplant if there was a possibility the organ was donated by an individual who made the decision to withdrawal life-sustaining treatment or receive medical aid in dying.

Rationales for and against deceased organ donation following MAID/WLSM

(Excerpted and adapted from: What do we know about deceased organ donation by the conscious, competent adult? A scoping review.)

Pros
• Could increase the number of organs available for donation(2-12) • These organs would likely be of better quality(8) • Respect for individual autonomy and self-determination(2, 4, 5, 13-16) • Personal benefit to the donor, whose own death may easier to bear if he or she knows that death will save or improve the life of another(4, 16) • Likewise benefit his or her family by providing increased solace or comfort during their grieving(4, 16) • Cost-effectiveness as a factor in favor of permitting organ donation in these circumstances(4, 12) • May increase public acceptance of assisted dying(12)
Cons
• May unduly pressure patients □ a person who may not otherwise opt for MAID might choose to die to donate his or her organs to help others(4) • Permitting organ donation following WLSM or MAID could undermine public trust in the organ donation system because “physicians would be tempted to be deliberately pessimistic about the patient’s prognosis to enhance the patient change of request for withdrawal of treatment”(13)

- Some maintain that all patients in these circumstances should be informed about the possibility of donating their organs(2, 11, 17)
  - this would support autonomy and justice by giving all potential donors the information with which they could make an informed choice(2, 15)
- By contrast, some argue that providing all patients with this information could be perceived as pressuring the patient to donate.(2)
- One factor that the physician may consider in making this decision is whether the patient has previously registered as an organ donor(15, 17)
- Trillium Gift of Life Network guidance document: states that approval to receive medical assistance in dying constitutes an “imminent death” and requires designated facilities to notify TGLN so that the individual may be approached(18)
- Quebec: disagreement between the CEST and Transplant Quebec regarding whether the patient should be approached(2)

The 2011 Canadian Blood Services System Ethics Consultation and 2014 End-of-life Conversations with Families of Potential Donors recommended the following:

1. Maximizing identification, referral and consent by ensuring the system offers proximate access to provide an opportunity for all types of donation consistent with public policy and broader societal values.
2. Approach the family of every potential donor and offer the opportunity for donation.
3. Notify the Organ Donation Organization as early as possible and before the initial donation conversation with the family.
4. The obligation is to inform and disclose appropriate information so that potential donors/surrogates can make an informed decision about donation.

5. The geographic location of a potential donor is appropriate to consider in that it impacts the availability of organ and tissue procurement teams and services may not be available in all communities. It is not mandatory to provide the service in all institutions, as long as there is proximate access to donation services, and donors or their families are informed of available options.

Provincial Legislative Review

A legislative review of provincial tissue gift acts shows that the provinces of BC, MB, ON, QC and NS have mandatory referral laws - the ODO must be notified when death is imminent or established. Alberta has mandatory consideration after death determination. At the time of this report, SK, NB, PEI and NFLD do not have legislation in this regard.

Figure 1: Sequence of Care in Deceased Donation in Relation to Notification and Referral

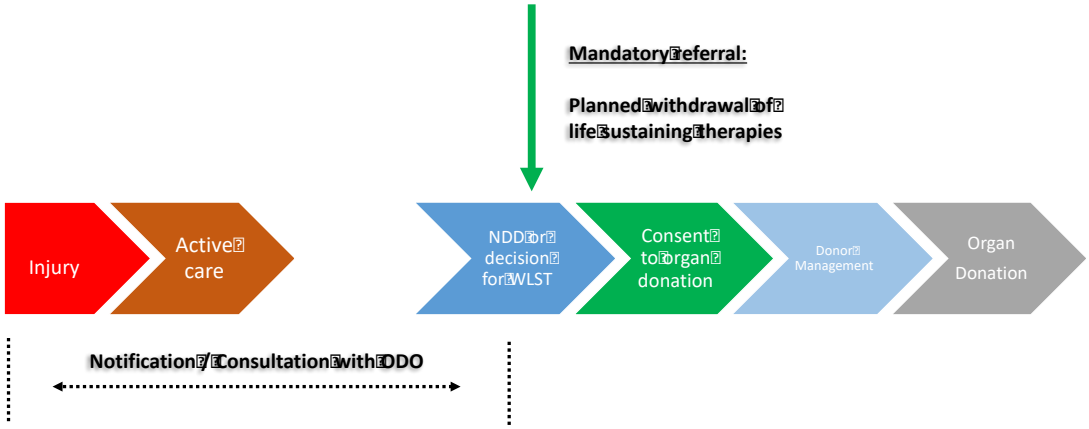

Table 1: Policies on organ donation in countries where medically-assisted death is permitted (adapted from Allard and Fortin, J Med Ethics, 2016)

Country or State	Policy on Organ Donation
Switzerland (assisted suicide by non-physician)	Not possible
Belgium (euthanasia)	Possible at patient's request 21 patients (2005-1015)[20]
Netherlands (euthanasia, assisted suicide)	Possible after euthanasia at patient's request Working on an official post-euthanasia donation protocol 15 patients (2012-2015)[21]
Luxembourg (euthanasia)	Illegal
Oregon, Washington, Vermont and Montana (assisted suicide)	Not Possible
Ontario, Canada	Routine request
Quebec, Canada	Patient initiated

Questions:

2. Please discuss and advise on roles of these teams and make recommendations for separation and/or alignment of duties in the EOL care process (T0-T4).
3. a. What are some of the unique challenges to consent discussions in this context?
   - At what point during the care plan for MAID/WLSM should the approach for OTD be made? Should there be a waiting period after decision for MAID- if so, please advise.
   - How should patient-initiated requests for OTD be managed when they occur prior to the MAID/WLSM consent discussion?
   - When should the Organ Donation Organization be notified? Who should conduct OTD consent discussions? Are there any distinct skill sets or characteristics that the health care provider making the request should have in these circumstances?
   - In what settings should the conversation occur?
4. Consider the following:
   1. How might a decision to proceed with MAID/WLSM impact on a decision to proceed with organ/tissue donation?
   2. How might a decision to proceed with organ/tissue donation impact on the preceding decision for MAID/WLSM?

   Consciousness and capacity will have been established as part of the first-person request/consent for MAID/WLSM. MAID patients must reaffirm consent prior to the MAID intervention.
   1. Think about factors that could unduly influence the MAID/WLSM decision. What standard questions or information, if any, might be included in donation consent discussions to protect patients from undue influence?
   2. Under what circumstances might the donation decision restrict the ability of the patient to change his/her mind about the EOL care decision? Provide suggestions on how you might mitigate this?
   3. Suggest mechanisms to provide ongoing patient support after OTD consent has been provided.
   1. Under what conditions, if any, would a re-assessment for capacity/competence be required prior to the donation decision?
   2. Currently, an individual who is opting for MAID must provide express consent at the time of MAID. Some patients may unexpectedly become incapacitated (loss of consciousness and capacity) after the MAID/WLSM decision and consent to donation.
   1. Please advise on if/how to proceed under these circumstances.
   2. How would you manage family veto (family override) of a patient's request to donate under these circumstances?
   3. How would you manage patient requests for confidentiality around the decision for MAID/WLSM in the setting of OTD?
   4. Under what conditions, if any, would patient requests for directed donation of transplantable organs be permissible?
   5. How would you manage requests for patients to become living organ donors prior to MAID/WLSM procedures?

Excerpted and adapted from: What do we know about deceased organ donation by the conscious, competent adult? A scoping review.

To be eligible, an individual must be 18 years of age and capable of making health care decisions, have a grievous and irremediable medical condition as defined by the legislation, have made a voluntary

request for MAID that is not the result of outside pressure or influence and give informed consent to receive MAID.(1)

Ethical considerations

- Patient may be influenced or coerced to donate organs(2, 4, 13, 15)
- Patient may feel pressured to consent to donation because he or she is dependent on a physician for withdrawal of care whom the patient may perceive as favoring donation(13, 17)
- Patients may choose to die in order to donate their organs to save the lives of others(4, 5, 15, 16) or may choose to end their lives earlier than they would otherwise, in order to donate(5)
- The act of informing patients of the opportunity to donate could put pressure on a patient(2, 12, 17)
- [pressure may be] exacerbated if they are aware of a specific recipient in need of an organ(15)
- The motivations for consenting to WLSM, MAID and donation must be carefully explored by the health care provider as part of the evaluation process
- Dutch practice manual warns against discouraging a patient's altruistic intentions if he or she otherwise meets euthanasia criteria: donation should not be discouraged or disallowed solely because a patient expresses altruistic motivation(15)

Other clinical/medical considerations

- Capacity to consent (e.g. "confirming that the individual has a fatal neurological illness, screening for and treatment of depression, and recognition that some patients have depression, pseudo-dementia or dementia.")(16)
  - "it is imperative to discuss what to do if the patient's condition deteriorates and the patient becomes unconscious in the days preceding the day of the procedure."(15)
- Increased cooperation between health care providers and institutions responsible for end-of-life care, organ procurement and transplantation(5, 8)
- Ensuring that a transplant coordinator is present during the meeting between the patient and the physician performing the withdrawal or MAID(15)
- Discussion should occur *after* the discussion regarding withdrawal of life-sustaining treatment or MAID(5, 11, 12, 17)
- Discussion about organ donation should be facilitated by the organ procurement team as opposed to the patient's treating physician(16)
  - others have suggested that "[t]he treating physician, who often has a long-term relationship of trust with the patient, is usually the preferred person to raise the issue of organ donation."(15)
- Creating specialized centres where organ donation following WLSM and/or MAID is performed(8)
  - Arrangements with the coroner(15)
  - For supports or debriefing mechanisms for health care professionals and medical staff who participate in these cases
    - these cases can be emotionally difficult(16)

Protections for patient/potential donor

The literature identifies several protections to safeguard the interests of the patient and to ensure that they provide free and informed consent to either the withdrawal of life-sustaining treatment or MAID as well as organ donation. These include:

- separation of decisions and processes
- ensuring separate teams for the WLSM or MAID procedure and the organ donation procedure(2, 4, 7, 8, 14, 15)
- separate medical teams protect the patient from the pressure discussed above
  - they may feel it is necessary to consent to donation in order to secure the assistance of the physician providing the WLSM or MAID.
- capacity to consent to WLSM/MAID and organ donation(6)
- waiting period will provide the patient with an opportunity to reconsider or withdraw consent to WLSM/MAID and/or organ donation

Directed donation

- Requesting withdrawal or MAID because he can donate organs either to someone specific(15) or in general
  - may be motivated by some other outside influence, such as financial considerations(18)
- Suggest prohibiting directed donation in this context(2, 15)
- Living organ donation is mostly directed and there is no explicit prohibition on directed deceased donation in Canada.(2)

Dutch Practice Manual points out that it is illogical that a patient undergoing euthanasia could designate a recipient by choosing to undergo living donation in advance of euthanasia, but that they would be prohibited from directing their deceased donation.(15)

Public perception

- Organ donation following MAID may "enhance the social acceptability of [assisted dying] practices."(4, 12)
- Risk that the "association of [organ donation and transplantation] with [assisted dying] could reduce the overall acceptability of [organ donation and transplantation] and possibly damage the trust and confidence that societal members currently have in standard/traditional organ donation and transplantation practices."(12)

Concerns may be mitigated by:

- first-person informed consent(12)
- transparent, consistent processes to promote public trust in the system(3, 6)
- separation of the decisions regarding MAID and donation(2)
- notification and request for permission to a coroner or public prosecutor to obtain the body for organ donation(8, 15)
- review by a regional euthanasia committee(15)

Key protections for Canadian context:

a. Separation of decisions regarding WLSM or MAID and organ donation;
b. Discussion of organ donation should occur only after the decision regarding WLSM/MAID has been made;
c. Separation of teams: end-of-life care team, organ procurement team and organ transplant team;
d. Coordination between these teams is needed to ensure that the patient receives the highest level of care and his or her wishes are respected to the extent possible.

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Questions:

Challenges may exist at individual and institutional levels in relation to offering MAID/WLSM, organ/tissue donation, conducting procedures for MAID/WLSM, surgical recovery of organs, transplant recipient acceptance of organs.

1. What kinds of accommodations should be made for health care providers who do not want to participate in the donation or transplant after MAID due to issues of conscience? What are the scope and limits in this regard? What should the responsibilities be of the health care professional who objects?
2. The process for MAID/WLSM/OTD may be emotionally difficult on HCP. Please provide suggestions on how to support HCP's involved in this process.

Procedural & Logistics

3. Discuss how to manage previously stated separation of duties and the need for coordination of clinical care, EOL care, MAID, WLSM, donation, surgical recovery and transplant logistics.
4. There are restrictions to EOL care in consented potential donors after MAID/WLSM. These may include a requirement of in-hospital location of MAID/WLSM procedures (e.g. ICU or operating room), door assessments and testing, evaluations of organ function, monitoring, pre-mortem interventions, immediacy of surgical recovery of organs after death. Informed consent would be required for all pre-mortem interventions.
    1. Are there other changes or restrictions to consider?
    2. Please advise on if/how to proceed under these circumstances.
5. There are no specific death determination recommendations in MAID practices. Are there any additional recommendations for death determination and monitoring at the end-of-life in MAID/WLSM donors?

Conscientious Objection (excerpted from Buchman et al 2017)

The health care professional encounters [conscientious objection when there is] tension between her or his personal and professional moral commitments.
Canadian law on MAID states that "everyone has freedom of conscience and religion under section 2 of the *Canadian Charter of Rights and Freedoms "nothing…compels an individual to provide or assist in providing medical assistance in dying".(5)*

Table 2: Summary of Key Themes

Theme	Summary
Lack of consensus on definition, scope, and limits	• The literature tends to support the notion of CO for health care providers, but there is no consensus on its scope or limits
The necessity, boundaries, and limits of a duty to refer	• The literature was divided between the position that a conscientiously objecting health care provider should refer the patient to a willing and available provider and the position that any degree of referral as being complicit in a morally wrong act
Participation and cooperation among	• Terms such as participation and cooperation are points of controversy in the MAID literature

interprofessional health care providers	• Some health care providers, such as nurses and pharmacists, may perceive themselves to be morally implicated in MAID even if they do not directly provide the MAID intervention
Tensions between conscience-based refusals and job security	6. Some health care providers may perceive that they have no power to CO to an act they find morally objectionable without risks to their employment
Potential harms to the donor and the transplant candidate	7. Scarce literature 8. Objecting to using organs from MAID donors may lead to patient deaths 9. Refusal does not respect patient's wish to donate

Summary

All citizens of Canada including Canadian health care providers enjoy the freedom of conscience and religion

- Given the controversy over MAID, some individual health care providers, transplant programs, or hospitals, may object to using organs from donors who died from MAID
  - this may delay, impede, or potentially prevent the use of organs for transplant and lives may be lost
- Objections to using organs based on how the person died may be inconsistent across health care providers and institutions
  - May lead to additional inequities into the organ donation and transplantation system

Procedural and Logistic

Excerpted and adapted from: What do we know about deceased organ donation by the conscious, competent adult? A scoping review.

Practical considerations

Potential effects of decision to donate:

- modifications to the patient's end-of-life care that will arise if he or she opts for organ donation
  - preparatory procedures, blood tests, and imaging(8, 15)
  - may consent to a series of pre-mortem interventions, such as the administration of heparin, which will maintain/improve the quality of his or her organs(2, 15)
- the place of death must be in hospital as opposed to at home(2, 4, 8, 15, 17)
  - facilitate optimal organ recovery and optimize transplantation success for the organs.(5, 15, 17)
- may impact the family's opportunity to say goodbye to their loved one and to grieve their loss(2, 15, 17)
  - patient must be transported to the operating room immediately after the physician has determined death(1
  - many families "appear very supportive of the patient's last wish despite the potential extra burden."(17)

Practical clinical issues

- circulatory death is determined(15)
- the short pre-mortem ischemic time associated with donation after MAID is a potential advantage over donation after WLSM(5)

Current Canadian death determination guidelines for DCD state: "Beginning with the onset of circulatory arrest, there must be a 5-minute period during which the absence of palpable pulses, blood pressure and respiration are continuously observed by at least 1 physician. Death is determined by 2 physicians by documenting the absence of palpable pulses, blood pressure and respiration on completion of this 5-minute period. The physician present during the 5-minute period of continuous observation and who makes 1 of the determinations of death must be a staff physician with the requisite skill and training. Monitoring to establish the fact of death is the priority during this period of observation. There must be no interventions to facilitate donation during this period. No physician who took any part in the determination of the fact of death of the donor shall participate in any way in transplant procedures. The

legal time of death is the determination after a 5-minute observation period. The purpose of the 5-minute observation period is to confirm the irreversibility of cardiocirculatory arrest before organ procurement. Blood pressure is defined as an arterial pressure that generates anterograde circulation. The preferred method to confirm the absence of blood pressure is by arterial line monitoring."
Bollen et al 2016: The Health Council of the Netherlands: "circulatory death is ascertained by recording the absence of an intra-arterial pressure wave or based on another current method of monitoring circulation. A no-touch period of five minutes is then observed. After this time has elapsed, irreversible circulatory and respiratory arrest exists, and death may be declared"

TGLN Draft MAID-Organ Donation Protocol

Patient may withdraw from the donation process at any point.

- For organ donation to occur, death must occur in the hospital in close proximity to the operating room.
- Screening for suitability will be required prior to the MAID provision and will involve facilitation of admission to the hospital at least two (2) days prior to the MAID provision (i.e. blood work, chest x-rays).
- Final determination of organ suitability for transplantation is made by individual transplant programs.
- Patient will not be suitable for organ donation if oral medication is used for the MAID provision.
- Heparin will be required prior to death.
- Process and location for medical suitability assessment.
- Arterial line insertion is required prior to the MAID provision.
- If the patient refuses or this cannot be facilitated, the DSP must be consulted for approval of an alternative method to declare death.
- Organ donation cannot and will not occur until after a patient is pronounced deceased as per standard medical practice mirroring the traditional process of donation after death by circulatory criteria (e.g. two physicians, arterial line)

Questions:

Eligibility to Donate

a) How should uncertainties for disease transmission in ALS donors and other end stage neurological diseases be managed?
b) How should end stage neurological diseases that have not been clearly diagnosed be managed in regard to OTD eligibility?

Transplant Implications

1. Regarding MAID or ALS donors, what information or disclosures if any, should be provided to transplant candidates? Please consider how maintain donor privacy.
2. Are there implications for transplant organ quality and allocation decisions?
3. Should there be a risk designation (e.g. exceptional distribution) assigned to organs transplanted from patients who have undergone MAID/WLSM? If yes, please advise.
4. What type of recipient follow-up would you recommend for potential transmission of neurological diseases?

Adapted from "Should ALS patients be organ donors? (Shoesmith and Shetter)"

ALS is a neurodegenerative disease which causes progressive degeneration of the motor neurons in the motor cortex of the brain and the anterior horn cells of the spinal cord. The disease typically begins with focal neurogenic weakness and can progress to generalized weakness. Common initial presentations of the disease are difficulty speaking, difficulty swallowing, hand weakness, or foot weakness. Where ever the weakness begins, the patient will experience progressive weakness in that body region and the weakness will spread to involve other body regions.

The diagnosis of ALS is made typically by a neurologist who confirms the diagnosis after reviewing: the patient's story, examination findings, electrophysiology results, and other investigations. Typical ALS physical examination signs are weakness, muscle atrophy, fasciculations, hyperreflexia, spasticity, and other upper motor neuron findings. Unfortunately, there is no single laboratory or electrophysiological test that can confirm a diagnosis of ALS. As a consequence of not having a specific diagnostic test, a diagnosis of ALS requires an experienced clinician to be able to suspect ALS based on a typical history and examination findings, and the necessity of ruling out ALS mimics through appropriate investigations. ALS has an incidence of 2-3 cases per 100 000 people.

About 10% of patients with ALS have hereditary ALS, which means that their disease is inherited in an autosomal dominant or autosomal recessive manner. The majority of patients with ALS have "sporadic ALS" which means that their disease has not been caused by any genetic mutations known to cause ALS and there is no evidence of other family members with ALS.

Although classically described as a predominately motor disease, ALS is now recognized to cause frontal executive, social cognition or behavioural impairments in a proportion of patients. On formal neuropsychological testing, 50% of patients with ALS will have frontotemporal cognitive impairments or behavioural impairments. Up to 40% of these patients with ALS will have sufficient cognitive or behavioural impairment to cause functional impairment and are classified as having frontotemporal dementia (FTD).

There are a few pharmacological treatments which have only demonstrated modest benefit in slowing the progression of ALS. patients with ALS will eventually die of respiratory failure. However, there are a number of respiratory interventions that can prolong survival in ALS. Specifically, non-invasive ventilation (NIV), invasive ventilation and mechanical in-exsufflators can support patients with significant

respiratory muscle weakness. Some patients with ALS start using non-invasive ventilation and slowly progress to using non-invasive ventilation for 24hours a day.

Avenues of potential organ donation from ALS patients

ALS is not known to cause any organ impairments outside of the brain and spinal cord. Although there is respiratory muscle weakness in ALS, the lung parenchyma should otherwise be normal. Patients with ALS often have interest in donation of their organs.

There are 3 ways that an ALS patient could potentially offer to donate their organs:

- Donation through DCD after discontinuation of invasive ventilation
- Donation through DCD after discontinuation of continuous non-invasive ventilation (NIV) support.
- Donation after Medical Assistance in Dying (MAID).

Evidence for or against the transmissibility of ALS

ALS research currently uses models of familial ALS to study the disease. Unfortunately, there are no great models of sporadic ALS that have been identified.

Evidence of ALS transmission in cell cultures

Authors of the papers often refer to the potential for prion-like capacity of ALS because of the protein inducing misfolding and/or aggregation seen in ALS models. The CSF from patients with ALS can serve as the seed to propagate the disease.

Evidence of ALS transmission in animal models

Fraser et al did an experiment in 1996 whereby they inoculated mice with brain and spinal cord homogenates from patients who had died of ALS. The inoculation was done both intracranially and intraperitoneally in separate mice and the mice were observed for 600-800 days. None of the mice developed ALS.

Transplantation of ALS organs has already occurred

Toossi and colleagues in 2012 reported that 12 ALS patients in the US had proceeded with DCD in the US prior to 2011. Smith and colleagues report 2 patients with ALS that elected to donate organs after DCD. It is unclear if the two patients that Smith reports are part of the twelve-patient cohort of Toossi et al, but the authors on the papers are different. A few ALS patients in Ontario have also donated their organs. There have been no subsequent published reports of transmission of ALS in any of the recipients of these organs from ALS patients.

Opinions of ALS transmissibility in the Canadian ALS research community

The literature review information contained in this report was presented to the Canadian ALS research community at the ALS Canada Annual Research Forum on April 30, 2017.

Question	Responses			
	Yes	No	Unlikely	Uncertain
Is ALS transmissible through organ transplantation?	0%	7.5%	55%	37.5%
Is ALS transmissibility risk different for sporadic vs hereditary ALS?	12.8%	28.2%	18%	41%
Are certain familial ALS mutations more likely to be transmissible?	21%	23.7%	-	55.3%
Should we transplant organs from ALS patients?	53.9%	12.8%	-	33.3%

- 52.5% of respondents indicated that they felt recipients of ALS organs should be informed that their organ came from a patient with ALS. 15% said that organ recipients should not be informed to protect the confidentiality of the donor. 32.5% were unsure if donor recipients should or should not be informed of the fact that their organ can from an ALS patient.

- The majority of respondents did suggest that transplant recipients of ALS organs should be monitored for the development of ALS and that reporting of ALS in transplant recipients should occur.

Summary Statements It cannot be definitively determined if ALS is or is not transmissible.

- It is likely that intracerebral or intraspinal transmission of ALS can occur. The blood brain barrier may protect against ALS transmission from solid organ transplantation.
- Organ recipients with genetic vulnerability for ALS (that is patients carrying ALS genetic mutations) may be more likely to develop ALS through transmission of protein misfolding. In other words, potential recipients with a first degree relative with ALS may be at higher risk of developing ALS from a transplanted organ from an ALS patient.
- If ALS is transmissible through organ transplantation, it will likely take more than ten years to develop. This estimate of ten years is taken from the human pituitary growth hormone database publication.
- Recipients need to be given the choice as to whether they would like to receive an organ from an ALS patient and they need to be informed that we are unsure if ALS is transmissible.
- Recipients of organs from ALS patients need to be followed closely for development of ALS for the duration of their lives. ALS transmission may not occur for over 15 years and so there should be long term follow up of these patients.
- Any transplant patient developing ALS or other neurodegenerative disease needs to have their status reported to their provincial transplant agency. This includes patients who did not receive an organ from a patient with a known neurodegenerative disease. Understanding the baseline risk of ALS in any solid organ recipient will be very important when assessing the correlation of development of ALS with the donated organ.

Adapted from Allard and Fortin, J Med Ethics, 2016

- Canadian public is not unanimous in its support of MAID. Some object to the practice on religious or ethical grounds.
- Potential recipients who oppose assisted dying may object to receiving an organ from a patient who has undergone MAID
- Some argue that potential recipients should be informed that their donor underwent MAID
- Some maintain that the source of the organs should not be disclosed
  - detailed information about the circumstances of a donor's death, including a violent non-assisted suicide, are not generally disclosed to potential recipients in certain jurisdictions, giving recipients the chance to refuse organs on these grounds would "lead to organ wastage and indeed to the potential death of the recipient"

Appendix 9: Acronyms

ALS	Amyotrophic lateral sclerosis
CACCN	Canadian Association of Critical Care Nurses
CEST	Commission de l'éthique en science et en technologie
CCCS	Canadian Critical Care Society
CCCS WLSM	Canadian Critical Care Society Guidelines for the Withdrawal of Life‑Sustaining Measures
CJD	Creutzfeldt Jacob Disease
CO	Conscientious Objection
CSF	Cerebrospinal Fluid
CSPCP	Canadian Society of Palliative Care Physicians
CST	Canadian Society of Transplantation
DCDD (or DCD)	Donation following Circulatory Determination of Death. Variably referred to as DCD - Donation after Circulatory Death, Donation after Cardio-circulatory Death or Donation after Cardiac Death
DNDD (or NDD)	Donation following Neurological Determination of Death
EAP	Employee Assistance Plan
ECMO	Extracorporeal Membrane Oxygenation
EOL	End-of-Life
FTD	Frontotemporal Dementia
HCP	Health Care Professional
ICU	Intensive Care Unit
MAID	Medical Assistance in Dying
MRP	Most Responsible Physician
NIV	Non-invasive Ventilation
ODO	Organ Donation Organization

OTD	Organ and Tissue Donation
SDM	Substitute Decision Maker
SOD1	Super Oxide Dismutase 1
TGLN	Trillium Gift of Life Network
WLSM	Withdrawal of Life-Sustaining Measures

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