

Feature

Medical assistance in dying for mental illness: a complex intervention requiring a correspondingly complex evaluation approach

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Medical assistance in dying for mental illness as a sole underlying medical condition (MAiD MI-SUMC) is a controversial and complex policy in terms of psychosocial and ethical medical practice implications. We discuss the status of MAiD MI-SUMC in Canada and argue for the use of the UK Medical Research Council's framework on complex interventions in programme evaluations of MAiD MI-SUMC. It is imperative to carefully and rigorously evaluate the implementation of MAiD MI-SUMC to ensure an understanding of the multiple facets of implementation in contexts permeated by unique social, economic, cultural and historical influences, with a correspondingly diverse array of outcomes. This requires a complexity-informed programme evaluation focused on context-dependent mechanisms and stakeholder experiences, including patients, service providers and other people affected by the policy. It is also important to consider the economic impact on health and social welfare

systems. Such evaluations can provide the data needed to guide evidence-informed decision-making that can contribute to safer implementation and refinement of MAiD MI-SUMC.

Keywords

Medical assistance in dying; mental illness; psychiatry; complex interventions; psychiatry and law.

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Canadian parliamentary Bill C-14, legalising medical assistance in dying (MAiD), received royal assent in 2016;¹ this was followed by provincial and territorial policies and, in some cases, legislation for implementation. Currently, MAiD is not allowed in Canada for individuals whose sole underlying medical condition is mental illness (MAiD MI-SUMC).² The possibility of permitting MAiD and MAiD MI-SUMC has solicited strong reactions, accompanied by intense debate from ethical, clinical and legal perspectives. As some European countries offer physician-assisted death to persons with mental illness, and Canada is actively considering it, MAiD MI-SUMC is already part of the healthcare landscape. Given that crucial scientific, clinical and ethical questions remain unanswered, a complexity-informed programme evaluation, focusing on multiple facets and potential outcomes of MAiD MI-SUMC, is warranted. This approach would generate important evidence concerning this intervention and would help to inform healthy debate and active oversight.

MAiD in Canada

To be eligible for MAiD in Canada, one has to be aged 18+ years, be eligible for health insurance, be capable of making healthcare decisions, have a 'grievous and irremediable'¹ medical condition and make a voluntary request without external pressure. As of the 2021 legislative amendment,³ natural death no longer has to be reasonably foreseeable. Safeguards include an assessment by two independent medical or nurse practitioners; consultation with a practitioner with expertise in the medical condition (if none of the assessors has it themselves); ensuring the person has given serious consideration to alternatives to relieve their suffering; the option to withdraw the MAiD request at any time; the need for final capable express consent immediately before the procedure; and a lapse of at least 90 days between the first assessment and

MAiD provision, which can be shortened if the person is at risk of an imminent loss of capacity to consent to the procedure. The current exclusion of persons with mental illness from access to MAiD was set to expire in 17 March 2023³ while a parliamentary review took place. This exclusion was recently extended to 17 March 2024.⁴

International context

MAiD, either by euthanasia or assisted suicide, is legal in The Netherlands, Belgium, Luxembourg, Switzerland, Canada, Spain, New Zealand, Germany and Colombia,^{5,6} along with some state jurisdictions in the USA and Australia.⁶ In 2020, Germany overturned an assisted suicide prohibition on grounds of unconstitutionality. The UK is considering the adoption of MAiD for terminally ill persons,⁷ and a parliamentary inquiry is currently in progress. Medically assisted deaths account for a fraction of all deaths, and, in jurisdictions where MAiD MI-SUMC is legal, mental illness as a main concern accounts for a fraction of all MAiD cases. In Canada, 31 664 medically assisted deaths for physical illness were reported between 2016 and 2021, constituting 3.3% of all deaths in the country.⁸ In 2021, cancer was the most frequent underlying condition (65.6%),⁸ and the loss of ability to engage in meaningful activities was the most frequently cited suffering (86.3%).⁸ Luxembourg, Switzerland, The Netherlands and Belgium currently allow MAiD for mental disorders.^{5,6} (Note that Bill C-7 and associated legislative materials use the term 'mental illness'. The term 'mental disorder' is commonly used in major diagnostic classification systems. These terms can also be used interchangeably or interpreted in particular ways depending on the context and stakeholders involved.) In The Netherlands, the latest official report indicated that there were 7666 assisted deaths in 2021, including 115 for a mental disorder.⁹ In Belgium, there were 2966 assisted deaths in 2022, including 26 for a mental disorder.¹⁰ This international

Table 1 Elements of complexity as per the UK-MRC and MAiD MI-SUMC

UK-MRC complex intervention definition	MAiD MI-SUMC components
Multiple and interacting components for service users	Multi-step process from initial awareness of availability of MAiD MI-SUMC to the final end-of-life intervention.
Multiple and interacting components for providers	Wide range of service providers involved in the multi-stage process, from awareness raising, training, quality assurance and capacity development to addressing or referring requests, conducting assessments and administering the end-of-life intervention.
Wide range of behaviours targeted by the intervention	Protective behaviours and risk behaviours related to well-being, treatment adherence, healthcare-seeking, self-harm and suicidality could be directly or indirectly influenced by the intervention.
Varying expertise and skills of stakeholders involved in administering and using the intervention	All stages of the process will depend on attributes, knowledge, skills, attitudes and behaviours of professionals across disciplines and those of individuals requesting MAiD MI-SUMC. These are external factors that add complexity to the implementation of the intervention.
Multiple target groups, settings or levels	MAiD MI-SUMC affects individuals with mental illness, families and healthcare workers. Other systems are influenced by the implementation of MAiD MI-SUMC: healthcare institutions, health and social service systems, healthcare professions and communities at large. Context characteristics not inherent to the intervention itself can also add complexity.
Flexible or adaptable intervention	Need to adapt to different healthcare systems across Canada's provincial and territorial jurisdictions. MAiD might be implemented with differing or additional safeguards for mental illness in contrast to those for physical illness.

experience reveals that some 1–2% of MAiD procedures involve mental disorders. Locally, it will be important to monitor rates of MAiD MI-SUMC, while also considering numbers of cases of MAiD in the context of comorbid mental and physical illnesses, something which is already legally permitted and is not being accounted for in the existing federal monitoring system.

Debates around MAiD MI-SUMC

Some of the major concerns debated in connection with MAiD MI-SUMC in Canada are similar to those arising in the UK when non-terminal illnesses⁷ are discussed. These include difficulties operationalising suffering and irremediability,^{11–13} the roles of systemic social marginalisation in generating suffering,^{2,14} suicidality in the context of MAiD requests and the non-terminal nature of mental disorders. Substantial ethical issues related to non-maleficence in all medical acts, dignity in dying and its circumstances, and autonomy to decide upon one's life also emerge. Although these concerns are not exclusive to MAiD MI-SUMC, the diverse and divergent nature of the perspectives of healthcare service providers, patients and other stakeholders what constitutes – or not – a grievous and irremediable mental illness becomes a factor that further increases complexity,¹⁵ despite being external to the intervention itself.

Evaluation of complex interventions

As a team of researchers and clinicians in the field of mental health, we believe that rigorous, multifaceted research and programme evaluation will be necessary to guide the safe implementation and refinement of MAiD MI-SUMC. The UK Medical Research Council (UK-MRC) framework for complex interventions^{15,16} has been developed to guide the evaluation of complex healthcare programmes. Here, we propose its application to MAiD MI-SUMC, given the intrinsic complexity of the whole of MAiD and the role of external complexity factors when considering its implementation for persons with mental illness (Table 1). It must be noted that the UK-MRC framework could also be applicable across the medical sciences and to instances of MAiD beyond mental illness. The UK-MRC framework^{15,16} emphasises the importance of generating complementary evidence, beyond efficacy and effectiveness, to guide the implementation and evaluation of the interventions of interest; it also acknowledges the need to accept the uncertainty inherent to complex research questions. Extending beyond randomised controlled trials, the UK-MRC recommends an evaluation focusing on intervention theory, engaging stakeholders, identifying

key uncertainties and refinement opportunities, and considering economic impacts.^{15,16}

Recommended evaluation of MAiD MI-SUMC

Stakeholder engagement

A longitudinal, complexity-informed programme evaluation is recommended to capture individual and system outcomes among diverse stakeholders involved in MAiD MI-SUMC. A wide variety of stakeholders should be engaged, including professionals directly involved with practice, education and regulation regarding MAiD MI-SUMC. Particular emphasis should also be given to the engagement of patients and families,¹⁷ to capture the lived experience of the MAiD MI-SUMC process. Stakeholder engagement should be implemented across all stages of a complexity-informed programme evaluation, constituting an essential first step in ensuring that evaluation initiatives are responsive to stakeholders' needs and the needs identified in various implementation contexts. By incorporating sustained engagement practices and identifying relevant individual- and systems-level outcomes, programme evaluations of MAiD MI-SUMC will be able to guide future refinements necessary to this complex intervention, its safeguards and practices, and training needs.²

A longitudinal, phase-based approach

A complexity-informed evaluation should be conducted throughout all phases of a MAiD MI-SUMC request, starting with an initial stage in which a requester seeks information, followed by a formalisation of the request, subsequent assessments, and a final stage in which an assessment outcome is reached and follow-through on that decision is provided. At each stage, needs, resources and processes pertaining to education, quality assurance, prospective oversight and clinical practices should be evaluated. Such an approach was recommended by the Canadian government's expert panel on MAiD and mental illness.² At any point during its implementation, MAiD MI-SUMC could affect patients, service providers, family members and other stakeholders, who should all be considered in programme evaluations.

Individually relevant outcomes

Individually, potentially relevant outcomes to be evaluated among patients and their families include the impact of MAiD MI-SUMC on self-stigma, hope for recovery, empowerment, quality of life,

distress relief or exacerbation, acceptability of programme processes, maintenance or withdrawal of the MAiD request, the ultimate end-of-life decision and associated grief, and the impact of a denied request. For healthcare workers, potentially relevant outcomes relating to the availability of MAiD MI-SUMC include moral conflict, reluctance or willingness to be involved, self-efficacy, work satisfaction and burn-out, perhaps differentially among psychiatrists versus other professionals. Stakeholder engagement is required to identify and prioritise outcomes relevant to each group. Some of these outcomes are being explored empirically in jurisdictions where MAiD MI-SUMC is legal. For example, a recent Belgian study¹⁸ has highlighted that the assessment process elicits tensions between the requesters' perceived empowerment and overburden experienced during the request and assessment phases. A Dutch study¹⁹ also illustrated positive and negative outcomes experienced by families, including hope for their loved one's recovery, caregiving burden and relief, and grief. These examples illustrate how positive and negative impacts can be identified in connection with different stages of a MAiD MI-SUMC process. In the case of healthcare workers, recent empirical studies have explored psychiatrists' preferences on their level of engagement²⁰ with MAiD MI-SUMC and their perceived conceivability²¹ of performing this intervention. These empirical outcomes exemplify the importance of a complexity-informed programme evaluation that is responsive to intended and unintended changes emerging in connection with the implementation of the complex intervention.

Systems-level outcomes

At the systems level, a complexity-informed programme evaluation should capture outcomes associated with the introduction of MAiD MI-SUMC, such as the development and deployment of trauma-informed education (to disseminate information, practices and tools among practitioners, patients and families that are sensitive to the consequences of adverse life events and their role in illness experience and expression), practice standards, skills training and capacity development. Other systems-level outcomes could include the potential for defensive practice and conflict within healthcare teams, as well as barriers and facilitators to fidelity and best practices and their implications from a quality-assurance perspective. As the practice of MAiD MI-SUMC evolves, challenges, unintended outcomes and improvement needs arise. This is exemplified by the first criminal case linked to MAiD MI-SUMC in Belgium,²² which evidenced the need to theorise and evaluate how multiple systems – in this case, peer and institutional regulatory systems – influence the actual implementation of MAiD MI-SUMC in its local context. A complexity-informed programme evaluation would help inform programme theory refinements that could subsequently lead to practice, training and regulatory improvements at the systems level.

Economic and social outcomes

Economic and social impacts of the implementation of MAiD MI-SUMC are also of importance as part of future programme evaluation initiatives. These include loss of productivity owing to requesters' disabilities or death, healthcare costs owing to increased availability of treatments and means of relieving suffering, changes in health equity – including potential age,²³ race and gender effects²⁴ – and social attitudes towards mental illness. Programme evaluations should also address illness characteristics, social determinants of health, approval rates and other descriptive metrics, some of which have already been put into place by the Canadian government.²⁵

Complexity-informed programme evaluation

Individual- and systems-level outcomes can be heterogeneous, given the nature of complex healthcare interventions and complexity-informed programme evaluations. A single set of generalisable outcomes might not suffice to inform evaluative conclusions.¹⁵ Choosing the most relevant outcomes could be based on the MAiD MI-SUMC domains identified by stakeholders as the most relevant, which would help to understand how the components and mechanisms of the complex intervention interact with a particular context.¹⁵ For example, in Canada, the implementation and regulation of healthcare programmes is within the purview of each province and territory. Consequently, stakeholders across jurisdictions may identify different impact domains and different outcomes. A complexity-informed programme evaluation would be responsive to this variation.


Relevant programme evaluation methodologies

In order to capture the complexity of an intervention such as MAiD MI-SUMC, along with complexity factors relating to stakeholders' diverse views and the contexts involved, relevant evaluation methodologies are needed. These include a realist evaluation²⁶ to identify what works for whom (primary service users, service providers, other stakeholders), how and under what conditions, by evaluating the implementation context of an intervention, the proposed mechanisms driving it and triggered (or prevented) outcomes.^{26,27} System mapping²⁸ – a method that engages stakeholders with the aim of theorising and illustrating the boundaries and components of a system influenced by an intervention – could assist stakeholders in formulating theories about the way in which MAiD MI-SUMC components interact within one or multiple systems and identify impacts caused by the implementation of the intervention in a specific context.

Other relevant methodologies include ethnographic methods to facilitate the analysis of uncertainties and the identification of unexpected practices, relationships or unexpected outcomes.²⁹ These could inform or challenge assumptions related to provider-recipient interactions, intervention acceptability, stakeholder involvement and implementation processes. An economic analysis¹⁵ of short- and long-term health and non-health outcomes within health and social service systems³⁰ could also be considered as a methodology that could help us to understand the economic impacts associated with the introduction of MAiD MI-SUMC. It is important to note that a thorough evaluation of MAiD MI-SUMC that uses a diversity of methodologies to capture a breadth of variables would generate large amounts of data. It will be important to conduct objective, stakeholder-engaged analyses to come to unbiased conclusions and to use these data to inform system change.

Conclusions

MAiD MI-SUMC is among the most controversial and complex policies of our time in terms of psychosocial and ethical medical practice implications. It is imperative to evaluate its implementation carefully, to ensure an understanding of the multiple facets of implementation in contexts permeated by unique social, economic, cultural and historical influences, with a correspondingly diverse array of outcomes. A complexity-informed programme evaluation focused on context-dependent mechanisms, stakeholder experiences – including those of patients and service providers – and the economic impact on health and social welfare systems could provide the data needed to guide evidence-informed decision-making that could contribute to safer implementation and refinement of MAiD MI-SUMC.

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Author contributions

H.B.-B. and L.D.H. conceptualised the manuscript. H.B.-B. drafted the manuscript under the supervision of L.D.H. D.C., M.G., V.S. and L.D.H. reviewed, critically appraised and edited the manuscript. All authors approved the final version.

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