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COMMENTARY

Clinical trial implications for study participants accessing medical assistance in dying

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The legalization of medical assistance in dying (MAID) in June 2016 expanded options for end-of-life care in Canada[1]. That change in the end-of-life topography created a need to explore the impact of MAID at multiple levels, including accommodating conscientious objection for health care professionals, supporting MAID assessors and providers, applying a quality improvement lens to the delivery of MAID, and clarifying the role of palliative care in supporting patients who choose to proceed with MAID. Empirical research and experience are providing more clarity on those and other emerging issues related to the new option. However, one area that has not been explored in the literature is the potential effect of MAID on clinical trial data. Given that cancer is the diagnosis leading to MAID in 64% of cases in Ontario (Office of the Chief Coroner/Ontario Forensic Pathology Service. MAID Data Statistics as of 31 July 2018), MAID has the potential to affect trial data—specifically, survival outcomes. In this commentary, we aim to identify one institution's nascent observations in that regard and to raise awareness about how MAID could affect clinical trial results.

DISCUSSION

Findings

As of August 2018, 78% of patients who received MAID within our institution had a diagnosis of advanced cancer; the provincial rate was, as already mentioned, 64%. Early in our data collection for MAID cases, we observed that a number of the cancer patients who elected to receive MAID were also enrolled in clinical trials or were on long-term follow-up as part of a clinical trial. In fact, during the 2-year period since the introduction of MAID, we calculate that 18% of all completed cancer cases involved patients on a clinical trial.

When reviewing our local data more carefully, we noted that most of our cancer patients who opted for MAID were felt by their assessors to have a prognosis of only days to a few weeks. That observation suggests that the effect of MAID on outcomes in oncology-related clinical trial data might be minimal. However, given the significant percentage of patients noted to be receiving MAID at our site, and given that the focus of most trials continues to be overall survival, it is posited that trial participants choosing MAID might potentially be influencing trial outcomes. That influence likely takes on additional significance given the limited gains in overall survival being measured in clinical trials that involve advanced metastatic disease. Further, MAID deaths as a percentage of overall deaths continue to increase, from a rate of 0.6% in the first 6 months after legalization to the 0.9% set out in Health Canada's second interim report of 30 June 2017—representing a 47% increase in 6 months. Based on the experience in other countries, that percentage could well continue to rise[2]. The frequency with which patients enrolled in clinical trials ultimately choose MAID might then similarly rise over time.

Call to Action

1. We believe that this early "signal" warrants further investigation. However, investigation should occur on a larger scale than at individual centres, because those data might not be generalizable. Comparative data and further research are therefore needed.
2. Current MAID providers should document whether and when their patients were on or being followed in a clinical trial at the time that MAID was delivered. Those statistics should similarly be captured as a standalone endpoint by clinicians conducting clinical trials.
3. The clinical trial community should undertake a biostatistical analysis to identify the impact, if any, that MAID might have on trial outcomes.
4. Clinical trial reporting of research participants who pursue MAID should not be censored as "lost to follow-up."
5. A statistically sound approach to how MAID deaths can be incorporated into trial reporting—specifically, mortality and overall survival reporting—should be developed.
6. Trials should not exclude patients considering MAID in the future provided that all other trial eligibility criteria are met.

SUMMARY

Further prospective data collection and a biostatistical analysis are needed before any conclusions can be drawn about the potential impact of MAID on cancer trial results. A research effort of this kind is particularly important

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given that federal reporting requirements do not track this metric, and we are unaware of any uniform clinical trial approach to collecting such data.

CONFLICT OF INTEREST DISCLOSURES

We have read and understood *Current Oncology*'s policy on disclosing conflicts of interest, and we declare that we have none.

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