Variability in withdrawal of life-sustaining therapies

Baseline patient acuity variables are insufficient to explain the observed variability in the withdrawal of life-sustaining therapies in severe traumatic brain injury. Hospital- and physician-based variability in end-of-life decision-making and prognostication are well known.[1–3] Turgeon and colleagues attempt to draw similar conclusions in severe traumatic brain injury in Canadian centres.[4] Prognostication based on the physician, rather than on patient factors, is a concern to intensive care unit (ICU) practitioners. However, a number of important methodologic concerns cloud — rather than illuminate — in Turgeon and colleagues' retrospective study.[4] Mortality ranged from 10.8% to 44.2% across different centres, with most deaths associated with the withdrawal of life-sustaining therapies. The variation in mortality rates, after adjustments for admission covariates (sex, age, pupillary reactivity and Glasgow Coma Scale score), was attributed to differences in withdrawal rates because of hospital and/or physician practices rather than patient acuity. Because baseline covariates did not appear to explain the differences in adjusted mortality rates, we are left to assume that no other clinical variables during ICU admission would have an impact on decision-making. These are strong conclusions in the absence of information regarding the severity and temporal evolution of the brain injury after ICU admission.

Turgeon and colleagues[4] provide no data on comparative and serial neuroimaging between patients, neurosurgical and neuroprotective interventions, such as ventricular drainage and decompressive craniectomy, and other prognostic tests (e.g., somatosensory evoked potentials). Most concerning is the lack of information about intracranial hypertension, its measurement, management and the response to medical and surgical interventions. The ability for ICU physicians to neuroprognosticate is not limited to admission variables. Without information about the evolution of brain injury, intracranial pressure and response to interventions, the data provided do not support conclusions about the observed effect of medical practices on mortality rates.

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The authors respond

We agree with Drs. Shemie and Fontela[1] that not all potential confounding variables could be considered in our study.[2] We did adjust for the strongest baseline clinical predictors of death in this population,[3,4] but as we indicated in our interpretation, variables that could not be evaluated may have also contributed to the observed variation (e.g., regional differences in referral patterns, case-mix, religious beliefs or personal preferences). We agree that the evolution of brain injury over time often affects recommendations by physicians to withdraw life-sustaining therapies. However, we also observed large inter-hospital variability in rates of death due to withdrawal of life-sustaining therapies during the first three days of care — a time frame that is arguably too early to form accurate predictions about neuroprognosis. The observed inter-hospital variation cannot likely be explained by systematic differences in the temporal evolution of the brain injury across centres as suggested, and we remain concerned that differences in practice patterns are also likely to be responsible.

Although our study conclusions may generate discomfort, we believe that variation in physicians' perceptions of neurologic prognosis for patients with severe traumatic brain injury likely contribute to the observed variability in rates of death following the withdrawal of life-sustaining therapies. We believe our study helps highlight the need for high-quality research to better inform neuroprognostication, so that we can help families decide when to continue — and when to stop — life-sustaining treatments for these patients.

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Enforcement of natural health product regulations

As a long-time advocate for a consistent, risk-based approach to health product regulation, Consumer Health Products Canada applauds the basic thrust of the *CMAJ* editorial "No regulatory double standard for natural health products."[1] Consumer health products used in the practice of self-care can make a positive difference in the lives of Canadians and contribute greatly to the cost-effectiveness of the Canadian health care system. However, natural health products can do this consistently only if

the regulatory system that authorizes their approval for sale is evidence-based and enforced in the marketplace.

More than seven years after they were introduced, the natural health products regulations are still not being fully enforced. The consumer confusion mentioned in the *CMAJ* editorial[1] is real and will not go away until all products on pharmacy and health food store shelves meet appropriate and consistent standards of safety and efficacy and are labelled in clear consumer language consistent with the terms of product approval — as would be required by the natural health products regulations were they fully enforced. The members of Consumer Health Products Canada, who derive about half of their sales from products regulated under the natural health products regulations, are eager for the regulations to be fully enforced, but others may be less eager because of the potential economic effect.

It is time to put the health of Canadians and, in view of the key role that evidence-based self-care can play in providing cost-effective care, the health of the Canadian health care system ahead of the economic interests of companies that don't want to comply with relatively modest regulatory requirements. Consumer Health Products Canada agrees with your editorialists that broader changes to health product regulations may be desirable and bring more consistency in the longer term. But in the meantime, simply enforcing the existing regulations would be a logical step and the minimum government should do to support Canadians who want to practise responsible self-care.

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1. MacDonald NE, MacLeod S, Stanbrook MB, et al. No regulatory double standard for natural health products. *CMAJ* 2011;183:2079.

***CMAJ* 2012. DOI:10.1503/cmaj.112-2022**

Correction

The C-CHANGE Initiative

In the guidelines "Harmonization of guidelines for the prevention and treatment of cardiovascular disease: the C-CHANGE Initiative,"[1] author Mark S. Tremblay's degree should have appeared as PhD.

Reference

1. Tobe SW, Stone JA, Brouwers M, et al. Harmonization of guidelines for the prevention and treatment of cardiovascular disease: the C-CHANGE Initiative. *CMAJ* 2011;183:E1135-50.

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