FOR THE RECORD

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One in six caregivers distressed

One in six people who provide informal care to seniors experience distress, and those who look after seniors with Alzheimer disease or other dementia are most at risk, according to a Canadian Institute for Health Information (CIHI) study.

The study, *Supporting Informal Caregivers — The Heart of Home Care*, found the vast majority (98%) of seniors receiving home care also relied on a spouse, adult child, friend or neighbour to provide emotional support and assistance in daily living activities, such as shopping, transportation, medication management, bathing, dressing and feeding (http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=download_form_e&cw_sku=SICGHHCPDF&cw_ctt=1&cw_dform=N).

While the majority of these informal caregivers are “coping,” some 16% are overwhelmed by the role, said Nancy White, manager of home and continuing care development at CIHI, in a press release (http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_20100826_e). “While care for a loved one can be fulfilling, it also can be quite challenging. It is important to identify caregivers who are at risk of burnout, which can result in the senior being institutionalized.”

The study indicates informal caregivers for seniors with cognition problems, such as forgetfulness or confusion, were more than three times as likely to feel distressed. Those cognition problems were most often related to Alzheimer’s or other dementia.

People caring for seniors who were depressed, demonstrated “socially inappropriate conduct” or resisted care were also at an increased risk of feeling distressed.

While only a small number of seniors in home care displayed aggres-

sive behaviour, such as verbal or physical abuse, the study found more than half of these had caregivers indicating some form of distress. That represents a rate more than three times higher than the study average.

Caregivers were also more likely to experience distress when caring for their spouse. One-quarter of people providing informal care to their spouse reported distress, and spouses were twice as likely to experience distress as a caregiver than any other family member.

“This can likely be attributed to the 24-hour nature of their role,” explained Kimberly Peterson, vice president of client services with the Champlain Community Care Access Centre, one of 14 community centres in Ontario, in the press release.

The chances of a caregiver experiencing distress were two and a half times greater for those who provided care for 21 hours or more per week, compared to those who provided only 10 hours or less per week.

There are more than 2 million informal caregivers in Canada, who contribute some \$25 billion to the country’s economy, according to the study, which looked at more than 130 000 seniors (age 65 years and older) who received publicly funded long-term home care in 2007–2008. — Lauren Vogel, *CMAJ*

Feds adopt wait-and-see strategy for funding of therapeutic clinical trial of liberation therapy for multiple sclerosis

Unconvinced that balloon venoplasty is a valid therapy for multiple sclerosis (MS), Health Minister Leona Aglukkaq says the federal government will not provide financial support for a pan-Canadian therapeutic clinical trial of Italian physician Dr. Paolo Zamboni’s

controversial liberation therapy “at this point in time.”

But if seven studies now being funded by multiple sclerosis societies in Canada and the United States provide some evidence that Zamboni’s proposition is valid, the government will provide support for a pan-Canadian therapeutic trial, Aglukkaq told a press conference on Sept. 1. An expert scientific working group will be struck to make that determination on the basis of the findings of the seven studies.

Aglukkaq indicated the decision was predicated on the recommendations of a blue ribbon international panel convened by the Canadian Institutes of Health Research (CIHR) which concluded that liberation therapy lacks scientific validity. “At this point in time, we do not have the evidence to proceed,” she said.

CIHR President Dr. Alain Beaudet told reporters that the current health risks of balloon venoplasty don’t justify a clinical trial. “We don’t have the evidence that the procedure is actually doing more good than harm,” he said.

Zamboni hypothesizes that multiple sclerosis is a vascular disorder caused by narrowing or blocking of internal jugular veins or the azygos vein, leading to accumulation of iron within the brain, which triggers a condition he calls “chronic cerebrospinal venous insufficiency (CCSVI).” His treatment seeks to eliminate the blockages using angioplasty.

The blue-ribbon CIHR panel was dismissive of Zamboni’s findings, saying his interventional trial, “in which the internal jugular or azygos veins were dilated with balloons, was an unblinded pilot study in which both patients and the treating physician knew that a treatment procedure was being performed. There was no control comparison group, i.e., patients with MS who had a catheter placed in a vein, but did not have a balloon dilation. Patients also remained on disease-modifying

drugs for their MS symptoms. In this study, no benefit on disability was seen for MS patients with the more progressive forms of MS. Finally, a high proportion (47%) of treated veins became narrowed again with the passage of time. It is also worth noting that the results of venous angioplasty reported are no better than those achieved with standard MS drug regimens" (www.cihr-irsc.gc.ca/e/42381.html).

There is no evidence that "venous insufficiency" for the brain or spinal cord contributes to multiple sclerosis, or plays a key role in its development, the panel said. "Cancer surgeons routinely tie off and remove one or both internal jugular veins during surgery to treat head and neck cancer, with no deleterious effects on patients. Blockage of one or both internal jugular veins, due either to injury or disease (e.g., stroke, venous thrombosis, cancer) has never been associated with MS. Furthermore, there is no evidence to date that any vascular diseases have resulted in MS. Also, as noted, patients with MS do not have any clinical or radiologic findings consistent with increased pressure in the veins draining the brain or spinal cord."

Moreover, there are risks involved. "The prevailing medical opinion is that while 'balloon angioplasty' for veins may be relatively safe, it is difficult to justify the procedure as the veins eventually will re-stenose. In addition, there is a distinct possibility that the damage to the inner lining of a vein (that happens when a vein is artificially dilated) can increase the risk of thrombosis (clotting) of that vein: such clots are unstable, and can break free, travel through the heart and block major vessels in the lungs. This sequence of events, known as pulmonary embolus, can cause debilitating lung disease or death."

"Insertion of stents into veins is not commonly performed because stents in veins may clot, or in rare cases may become dislodged and move towards a patient's heart — such an event was reported in a patient following a venous angioplasty procedure. Venous stent placement usually requires the use of blood thinners, which have their own complications, including bleeding.

Potentially fatal outcomes due to the migration of a venous stent into the heart have been reported. There are also risks of brain hemorrhage associated with blood thinner use which can lead to stroke or death."

In short, "there is currently no scientifically valid evidence in support of the existence of CCSVI in patients with MS, and there is currently no scientifically valid evidence to support the use of venous angioplasty in the treatment of patients with MS," the blue-ribbon panel concludes. — Wayne Kondro, *CMAJ*

Experts call for fewer restrictions on the availability of pain medications

Treatments for acute and chronic pain should be considered a fundamental human right and be made more readily available to patients, concluded delegates to the first International Pain Summit in Montréal, Que.

The 10-article *Declaration of Montreal* emerging from the summit asserts that people in pain have a right to appropriate medicines such as opioids and morphine, that chronic pain should be considered a disease and that pain should be recognized as a "fifth vital sign."

The declaration indicates that pain management for 50% of people living in developed countries and 90% of people living in developing countries is inadequate. It estimates that one in five people worldwide have chronic noncancer pain (www.prnewswire.com/news-releases/health-care-professionals-and-advocates-from-84-countries-to-issue-declaration-that-access-to-pain-management-is-a-fundamental-human-right-102137469.html)

Although the final wording of the declaration is still being crafted, the delegates issued a version to the media in which they call on governments to recognize 10 human rights associated with pain management, as follows:

"Article 1. The right of all people to have access to pain management without discrimination, in particular, on the basis of age, sex, gender, medical diagnosis, race, religion, culture, marital

status, or political or other opinion.

Article 2. The right of people in pain to be informed about how their pain can be assessed and the possibilities for treatment. Recording the results of assessment, e.g. as the '5th vital sign', can focus attention on unrelieved pain, triggering appropriate treatment interventions and adjustments.

Article 3. The right to access an appropriate range of effective pain management strategies, supported by policies and procedures that must be appropriate for the particular setting of health care and the health professionals employing them.

Article 4. The right of people with pain to have access to all appropriate medicines, including but not limited to opioids, and to have access to health professionals skilled in the use of such medicines. In resource-poor countries it is important to at least ensure access to oral immediate-release morphine.

Article 5. The right of people with pain to assessment and treatment by an appropriately educated and trained interdisciplinary team at all levels of care. (In resource-poor countries the team should include, at a minimum, a doctor and a nurse with training in pain management).

Article 6. The right of people with pain to treatment under a health policy framework that is compassionate, empathetic, and well-informed. This includes legal systems (including laws relating to opioids), the conditions of employment that employers impose on employees, compensation systems, insurance bodies, and government agencies.

Article 7. The right of people with pain to have access to best practice nonmedication methods of pain management (ranging from relaxation and physiotherapy methods to more complex cognitive behavioral treatment) and to specialist-performed interventional methods, depending upon the resources of the country.

Article 8. The right of people with chronic pain to be recognized as having a disease entity, requiring access to management akin to other chronic diseases.

Article 9. The obligation of all health care professionals in a treatment relationship with a patient, within the scope of the legal limits of their professional practice and taking into account the

treatment resources reasonably available, to offer to a patient in pain the management that would be offered by a reasonably careful and competent health care professional in that field of practice. Failure to offer such management is a breach of the patient's human rights.

Article 10. The obligations of governments and all health care institutions, especially hospitals, within the scope of the legal limits of their authority and taking into account the health care resources reasonably available, to establish laws, policies, and systems that will help to promote, and will certainly not inhibit, the access of people in pain to fully adequate pain management. Failure to establish such laws, policies, and systems is unethical and a breach of the human rights of people harmed as a result." — Wayne Kondro, *CMAJ*

United States Food and Drug Administration rolls out performance tracker

In a bid to meet United States President Barack Obama's requirement that government activities be made more transparent, while bolstering its own credibility with the general public, the US Food and Drug Administration has unveiled a "performance tracker" that will allow the public to monitor the operations of more than 100 of the agency's program offices.

FDA-TRACK (for transparency, results, accountability, credibility and

knowledge-sharing) "will bring the operations of this historically opaque Agency into the daylight and help us be even more responsive as we work to protect the public health," said FDA Commissioner Dr. Margaret Hamburg in a press release (www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm224401.htm).

The tracker "monitors performance indicators in four categories: common measures, key center director measures, program measures, and key projects," the FDA stated.

"Common measures are agency-wide measures that are applicable to each of the program offices and may focus on the agency's most recent priorities. An example includes increasing the total number of employees who have completed the Incident Command System (ICS) training in the month, which helps the agency respond to emergencies," the FDA states in its description of the tracker (<http://www.fda.gov/AboutFDA/Transparency/track/default.htm>).

"Key Center Director measures are Center-specific measures that are applicable to each Center and are central to the Center's priorities and strategic goals. An example includes monitoring the percentage of employees who receive training each month, which enables the Center for Devices and Radiological Health to ensure it is providing high value training opportunities to its employees."

"Program measures are program office-specific measures that are applic-

able to the office and reflect work important to the public and FDA's mission. An example includes increasing the percentage of 510(k) (or Class II medical devices) decisions made on time during the month."

"Key projects are program office-specific projects that are applicable to the office and important to the mission and objectives of the office. Performance for key projects is measured through achievement of the established milestones within its project plan. An example includes the development of a new risk-based approach for evaluating safety, effectiveness, and quality of new animal drugs."

The performance indicators are among a raft of transparency measures that the FDA has created in response to Obama's Open Government Directive (www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-06.pdf).

The FDA transparency data sets and tools (www.hhs.gov/open/plan/open-governmentplan/transparency/dataset.html#track), include a Web-based curriculum describing the agency's regulatory responsibilities (*CMAJ* 2010; DOI:10.1503/cmaj.109-3157), as well as a Reportable Food Registry that will contain information "about foods for which there is a reasonable probability that the article of food will cause serious adverse health consequences or death." — Wayne Kondro, *CMAJ*

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