

FOR THE RECORD

MCC to stiffen licentiate requirements

A Medical Council of Canada (MCC) imprimatur that a would-be physician has the competence to practice should only issue after candidates have completed their residency requirements and achieved specialty certification, a blue-ribbon task force recommends.

As a part of a bid to develop more of a standardized national program for measuring the readiness to practice of both physicians in training and international medical graduates, as well as a national approach toward continuing assessment of physicians, the Assessment Review Task Force of the MCC is proposing that the requirements for a Licentiate of the MCC (LMCC) be expanded beyond holding a recognized MD degree and successful completion of both parts of MCC qualifying examinations.

“The LMCC must be a meaningful credential and reflect the level of training required for entry into practice,” the task force says in its report, *Recalibrating for the 21st century* (www.mcc.ca/pdf/ARTF_report_en.pdf). “The LMCC will have more value if it is awarded when a person is ready for licensure. A ‘new designation’ of the LMCC would mean a national qualification for entry into independent practice as the most responsible physician.” To that end, it proposes that requirements for the LMCC include a recognized MD degree, completion of both exams, “formal postgraduate education acceptable to the medical regulators” and certification from the College of Family Physicians of Canada, Collège des médecins du Québec, or the Royal College of Physicians Surgeons of Canada.

The task force also recommends that the MCC revise its current examinations, or develop new tools, to better assess the competencies of a candidate,

including his ability to: “Gather and integrate information, Develop a differential diagnosis and a treatment plan, Address the clinical problem effectively through critical appraisal and self-reflection, Demonstrate inter-professional collaboration, Demonstrate and discuss patient safety principles, and Demonstrate knowledge of the health-system structure and functioning.” It also recommends that there be more flexibility in the schedule of qualifying exams, possibly by offering them more frequently.

Arguing that provincial and territorial medical regulatory authorities have indicated a desire for assessments of international medical graduates (IMGs) “that are valid, reliable and appropriate,” the task force recommended that the MCC overhaul its exams for foreign physicians, while also “developing and standardizing other tools necessary to screen and assess IMGs coming to Canada for the purpose of entry into postgraduate training.”

With a trend towards more frequent revalidation of physician licences to practice, the task force also urges that the MCC and other professional bodies initiate a process to “develop a collaborative framework and an integrated national strategy for competency assessment and/or performance appraisal of physicians throughout their medical careers.” — Wayne Kondro, *CMAJ*

Formal supports for informal caregivers

Canada is overly dependent on informal caregivers to bridge the gaps in care for its aging population, yet underinvests in public programs to support them in that role, according to an Institute for Research on Public Policy study that calls for the federal government to establish a comprehensive long-term home care system.

In Canada, “it is assumed that a large amount of family care is available; family caregivers do not benefit from any direct public support. The health care system acts as a safety valve when family care is not available or not sufficient. And, at the point of entry into the health care system, policy typically is oriented toward the older adult, not the needs of caregivers or the caregiving unit,” Canadian Association on Gerontology president Neena Chappell explains in the study, *Population Aging and the Evolving Care Needs of Older Canadians* (www.irpp.org/pubs/IRPP_study/IRPP_Study_no21.pdf).

Citing studies that indicate that informal caregivers provide 75% to 85% of the total care received by seniors, the study states that “conservative” estimates indicate that “informal caregivers, aged 45 and over, provide approximately \$25 billion of care yearly to older adults in Canada.”

Most do so willingly and “despite the many documented demands and burdens of this role, and the sacrifices made in order to provide care, family members are not seeking to relinquish this caring role,” the study adds. “Nevertheless, demands sometimes become overwhelming, putting caregivers at risk of their own health deteriorating, not to mention potentially putting the older adult at risk through lack of proper care.”

The caregivers also typically receive little in the way of support, the study states. “Typically the only service that is targeted to caregivers is respite care, appearing in three guises: sitter attendance services giving short breaks to the caregiver to run errands, go to a doctor’s appointment and so on; adult daycare, where the older adult leaves the home for a few hours a week; and respite care beds within nursing homes for short stays. At the present time, there are no other programs that target caregivers, and in some jurisdictions (for

example, British Columbia), caregivers are eligible for respite services only when the older adult is already receiving formal care services. Those who are doing such a good job that the recipient does not need formal services are, by definition, not considered for support.”

The study argues that spending on home care was sacrificed in favour of spending on physicians, drugs and hospital-based acute care over recent decades. It also projects that the need for home care will be exacerbated as the population ages and the number of outpatient surgeries increases. As a consequence, there will be “demand for more short-term, intensive post-hospital home care, which current evidence suggests is redirecting resources away from long-term home care at a time when the size and care needs of Canada’s elderly population are increasing.” There’ll also be fewer caregivers available. Lower fertility rates and increasing rates of divorce, remarriage and blended families mean “more seniors will depend on fewer individuals for the care they need” in years to come.

A comprehensive strategy would address such factors as when and where to provide formal care in the absence of informal care, taking into account such factors as whether or not to base it on financial need. Long-term home care would be a “cost-effective” and critical component of that strategy.

That would necessarily have to include greater supports for caregivers, the study argues. Such supports have typically taken the form of “arrangements outside of the formal health care system, including voluntary organizations, churches and other not-for-profit and neighbourhood organizations,” as well as informal networks of friends and neighbours. The health care system, however, is “not organized to act as a coordinator or broker for bringing such resources together.”

A long-term home care program could “link and partner with informal caregivers and with community voluntary and not-for-profit as well as for-profit organizations that may form the support network for informal caregivers and older adults,” the study argues. “The formal health care system, in

other words, should not remain isolated but must find ways to work with other individuals, groups and organizations to the benefit of older adults.”

The report also argues for a more evidence-based approach to the interventions used in home and long-term care. “It is imperative that beliefs and assumptions be made explicit and evidence be fairly adjudicated. To date, much evidence is ignored on the sustainability of universal, public systems of care; the greater cost of care in for-profit delivery; as well as the cost-effectiveness of home care compared with institutional care. In other words, policies and programs are put in place without evidence of their appropriateness or effectiveness. For example, we lack evidence that many of the interventions in current use have increased quality of life or prevented a decline (such as the use of cholinesterase inhibitors in the treatment of dementia or, as many reports have pointed out, the increased use of diagnostic tests in older adults). It is also imperative that issues beyond the scope of this paper — such as increased technological innovations and pharmaceutical intervention that are known cost drivers — be tackled. It is essential that the broader issue of increased medical intervention be addressed. An independent council or some other mechanism for assessing effectiveness of interventions could be put in place,” as recommended by the Royal Commission on the Future of Health Care in Canada headed by Roy Romanow.

“The issue of evidence-based medical practice, which bases practice and funding on scientifically demonstrated effectiveness, cannot be ignored if the goal is a cost-effective and appropriate health care system for an aging society,” the study adds. — Lauren Vogel, *CMAJ*

New paradigm of pain

The United States needs to adopt a new paradigm for assessing treating and preventing chronic pain, which costs the health care system “at least” US\$560 billion in health care costs and US\$297 billion in lost productivity, the US Institute of Medicine says.

“Because pain often produces psychological and cognitive effects — anxiety, depression, and anger among them — interdisciplinary, biopsychosocial approaches are the most promising for treating patients with persistent pain. But for most patients (and clinicians), such care is a difficult-to-attain ideal, impeded by numerous structural barriers — institutional, educational, organizational, and reimbursement-related. Costly procedures often are performed when other actions should be considered, such as prevention, counseling, and facilitation of self-care, which are common features of successful treatment. In addition, adequate pain treatment and follow-up may be thwarted by a mix of uncertain diagnosis and societal stigma consciously or unconsciously applied to people reporting pain, particularly when they do not respond readily to treatment,” according to the Institute of Medicine study, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (www.nap.edu/catalog.php?record_id=13172#toc).

The institute called on the US Department of Health and Human Services to develop “a comprehensive, population health-level strategy for pain prevention, treatment, management, education, reimbursement, and research that includes specific goals, actions, time frames, and resources.” Among other things, the strategy should craft public and private initiatives “to encourage population-focused research, education, communication, and community-wide approaches that can help reduce pain and its consequences and remediate disparities in the experience of pain among subgroups of Americans.” It should also develop a national research agenda for pain and “improve pain assessment and management programs within the service delivery and financing programs of the federal government.”

Pain treatment is typically altogether haphazard, the study adds. “Currently, large numbers of Americans receive inadequate pain prevention, assessment, and treatment, in part because of financial incentives that work against the provision of the best, most individualized care; unrealistic

patient expectations; and a lack of valid and objective pain assessment measures. Clinicians' role in chronic pain care is often a matter of guiding, coaching, and assisting patients with day-to-day self-management, but many health professionals lack training in how to perform this support role, and there is little reimbursement for their doing so. Primary care is often the first stop for patients with pain, but primary care is organized in ways that rarely allow clinicians time to perform comprehensive patient assessments. Sometimes patients turn to, or are referred to, pain specialists or pain clinics, although both of these are few in number. Unfortunately, patients often are not told, or do not understand, that their journey to find the best combination of treatments for them may be long and full of uncertainty."

To improve the situation, clinicians should "promote and enable self-management of pain," the institute recommends. Patients should be provided with educational materials that contain "information about the nature of pain; ways to use selfhelp strategies to prevent, cope with, and reduce pain; and the benefits, risks, and costs of various pain management options. Approaches and materials should be culturally and linguistically appropriate and available in both electronic and print form."

Other recommendations included:

- "Health professions education and training programs, professional associations, and other groups that sponsor continuing education for health professionals should develop and provide educational opportunities for primary care practitioners and other providers to improve their knowledge and skills in pain assessment and treatment, including safe and effective opioid prescribing.
- Payers and health care organizations should work to align payment incentives with evidence-based assessment and treatment of pain. Optimal care of the patient should be the focus.
- The National Institutes of Health should designate a specific institute to lead efforts in advancing pain research." — Wayne Kondro, *CMAJ*

Crackdown on counterfeit drugs

The Council of Europe is proposing that the manufacture, supply or sale of counterfeit drugs and other medicinal products or devices for human or veterinary use be made a criminal offence because of the threat they pose to public health.

Under the "medicrime" convention inked by 12 of the council's 47 members in Moscow, Russia, in early November, it would also be illegal to "offer to supply" a counterfeit product or to falsify or intentionally tamper with documents related to medicinal products. The same would apply to any attempt to adulterate a product by making it "poorer in quality by intentionally adding or substituting another undeclared substance." And in a bid to stamp out any manner of collusion, "aiding or abetting and attempt" to counterfeit medical products would also be illegal.

Signatory nations would also be compelled to introduce legislation that result in corporate liability for medical counterfeiting "when committed for their benefit by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it based on: a power of representation of the legal person; an authority to take decisions on behalf of the legal person; [or] an authority to exercise control within the legal person" (www.coe.int/t/DGHL/StandardSetting/MediCrime/Medicrime-version%20bilingue.pdf).

Penalties would include jail time for those who manufacture or traffic in counterfeits. "Each Party shall take the necessary legislative and other measures to ensure that the offences established in accordance with this Convention are punishable by effective, proportionate and dissuasive sanctions, including criminal or non-criminal monetary sanctions, taking account of their seriousness. These sanctions shall include, for offences established in accordance with Articles 5 [manufacturing] and 6 [supplying or trafficking], when committed by natural persons, penalties involving deprivation of lib-

erty that may give rise to extradition." So jail time must be of at least a one-year duration.

Sanctions should be even more acute when the medicrimes involved "aggravating circumstances" such as:

- "the offence caused the death of, or damage to the physical or mental health of, the victim;
- the offence was committed by persons abusing the confidence placed in them in their capacity as professionals;
- the offence was committed by persons abusing the confidence placed in them as manufacturers as well as suppliers;
- the offences of supplying and offering to supply were committed having resort to means of large scale distribution, such as information systems, including the Internet;
- the offence was committed in the framework of a criminal organisation;
- the perpetrator has previously been convicted of offences of the same nature."

The convention is also unique in its use of public health and human rights, rather than intellectual property rights or drug safety, as the rationale for criminalization. "Counterfeiting of medical products and similar crimes violate the right to life as enshrined in the European Convention on Human Rights and Fundamental Freedoms, as these criminal and dangerous conducts effectively deny patients the necessary medical treatment and may often be harmful to their health, sometimes even leading to the death of the patient or consumer," the Council argues in an explanatory note to the convention (<http://conventions.coe.int/Treaty/EN/Reports/Html/211.htm>).

"The reason for the strong growth of this type of crime is clearly the relatively low risk of detection and prosecution compared with the potential high financial gains. Using the internet to advertise and supply their inherently dangerous products directly to patients and consumers around the world has proven to be a safe and easy modus operandi for the criminals involved and has given them a global reach. The result is a serious threat to public health of truly global proportions," the explanatory note adds.

While 12 countries — Austria, Cyprus, Finland, France, Germany, Iceland, Israel, Italy, Portugal, Russia, Switzerland and Ukraine — signed the convention during the meeting in Moscow, it must be ratified by at least five signatories before it can come into force. That is expected to occur in 2013. The Council of Europe was struck in 1949 to promote cooperation and standardization of European legal standards and human rights law. — Wayne Kondro, *CMAJ*

The government's right hand

The United Kingdom's General Medical Council (GMC) has proposed that doctors start encouraging patients to get off the dole and return to work as both a critical element of clinical success and a measure of good medical practice.

A new draft of the council's *Good Medical Practice* guidance, proposes that doctors "must support patients in caring for themselves to empower them to improve and maintain their health. This may include encouraging patients, including those with long-term conditions, to stay in or return to employment or other purposeful activity. You may also advise patients on the effects of their life choices on their health and well-being and the possible outcomes of their treatments" (www.gmc-uk.org/Good_Medical_Practice_2012__Draft_for_consultation.pdf_45081179.pdf).

Encouraging patients to return to work or to continue working, which the government has long sought of physicians, is among a number of new areas into which *Good Medical Practice 2012* ventures. Others include a directive to factor patient's social and spiritual histories into diagnosis and treatment.

Good clinical care, the draft guidance states, involves "adequately assessing the patient's conditions, taking account of their history (including the symptoms, and psychological, spiritual, religious, social and cultural factors), the patient's views, and, where necessary, examining the patient."

"This guidance makes clear that a doctor's responsibilities do not begin

and end with providing clinical treatment. They have a vital role to play to improve standards of basic care," Niall Dickson, the chief executive officer of the council said in a press release (www.gmc-uk.org/news/10795.asp).

"Good Medical Practice is about more than setting a minimum 'bar' below which standards of practice must not fall, or against which disciplinary action is taken. It must be a means of promoting excellent care and fostering the leadership and commitment that lie at the heart of medical professionalism," he added.

The draft guidance is open for consultation through Feb. 10, 2012 with an eye toward publication of a new edition later in 2012. The current edition of the guidelines was published in November 2006.

The council also indicated that it will be venturing into more new territory in 2012 by publishing specific guidance on physician use of social networking sites. For now, the good medical practice guidance states that physicians "should remember when using social networking sites that communications intended for friends or family may become more widely available."

The council will also be updating its guidelines on patient safety and its guidance on financial conflict-of-interest over the course of next year.

Among the provisions regarding patient safety included in the 2012 good medical practice guidance is one that says physicians "must take prompt action if you think that patient safety is or may be seriously compromised by inadequate premises, equipment or other resources, policies or systems."

The guidance argues that physicians have a duty to report colleagues to regulatory authorities. "You must protect patients from risk of harm posed by another colleague's conduct, performance or health. If you have concerns that a colleague may not be fit to practice and may be putting patients at risk you must promptly: a) discuss your concerns with a colleague (if possible one who does not work closely with the colleague you have concerns about) or contact your defence body, a professional organisation, or the GMC for advice; b) explain your concerns to

your employer or contracting body and follow their procedures; c) inform the regulatory body if the problem is not resolved by local procedures and patients are still being put at risk."

The guidance also says that physicians must take action to prevent patients from risk posed by their own health. "If you know or suspect that you have a serious condition that you could pass onto patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must comply with their advice about changes to your practice that they consider necessary. You must not rely on your own assessment of the risk to patients."

As well, "you should be immunised against common serious communicable diseases (unless otherwise contraindicated)."

While indicating that council guidelines on financial and commercial interests will be updated in 2012, the good medical practice guidance calls for "honesty in financial dealings" and states that physicians:

- "Must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals, declaring any interest that you have.
- You must not allow any interests you have to affect the way you prescribe for, treat or refer patients.
- If you are faced with a conflict of interests, you should be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.
- You must not ask for or accept — from patients, colleagues or others — any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients. You must not offer such inducements.
- You must act in your patients' best interests when making referrals and when providing or arranging treatment or care."

The guidance also argues that physicians must be more honest with patients when medical errors occur. "You must be open and honest with patients if

things go wrong. If a patient under your care has suffered harm or distress, you must: a) put matters right (if that is possible); b) offer an apology; c) explain fully and promptly what has happened and the likely short-term and long-term effects.” — Wayne Kondro, *CMAJ*

Patient safety largely ignored in electronic health systems

Health information technologies are inadequately regulated and often implemented or utilized without regard to the consequences for patient safety, according to a report by the United States Institute of Medicine.

“Currently, there is no systematic regulation or sense of shared accountability for product functioning, liability is shifted primarily onto users, and there is no way to publicly track adverse outcomes,” such as death and injury caused by misdiagnosis, surgical mishaps, drug reactions and other forms of medical error, the institute’s Committee on Patient Safety and Health Information Technology states in a report, *Health IT and Patient Safety: Building Safer Systems for Better Care* (www.nap.edu/catalog.php?record_id=13269).

To redress that, the Institute of Medicine recommends a number of institutional measures to oversee health information technologies (IT), including the creation of an “independent federal entity for investigating patient safety deaths, serious injuries, or potentially unsafe conditions associated with health IT. This entity should also monitor and analyze data and publicly report results of these activities.” The institute also urged that the US Food and Drug Administration be obliged to “immediately” begin developing a regulatory framework for health IT.

The report notes that while health information technologies were held out to have a transformative effect on the way health care is delivered, their impact on patient safety is unclear.

“Designed and applied inappropri-

ately, health IT can add an additional layer of complexity to the already complex delivery of health care, which can lead to unintended adverse consequences, for example dosing errors, failing to detect fatal illnesses, and delaying treatment due to poor human–computer interactions or loss of data,” the report states.

The evidence assessing the impact of health IT on patient safety is “mixed but shows that the challenges facing safer health care and safer use of health IT involve the people and clinical implementation as much as the technology,” the report adds. “The literature describes significant improvements in some aspects of care in health care institutions with mature health IT. For example, the use of computerized prescribing and bar-coding systems has been shown to improve medication safety. But the generalizability of the literature across the health care system may be limited. While some studies suggest improvements in patient safety can be made, others have found no effect. Instances of health IT–associated harm have been reported. However, little published evidence could be found quantifying the magnitude of the risk.”

“Several reasons health IT–related safety data are lacking include the absence of measures and a central repository (or linkages among decentralized repositories) to collect, analyze, and act on information related to safety of this technology. Another impediment to gathering safety data is contractual barriers (e.g., nondisclosure, confidentiality clauses) that can prevent users from sharing information about health IT–related adverse events. These barriers limit users’ abilities to share knowledge of risk-prone user interfaces, for instance through screenshots and descriptions of potentially unsafe processes. In addition, some vendors include language in their sales contracts and escape responsibility for errors or defects in their software. ... The committee believes these types of contractual restrictions limit transparency, which significantly contributes to the gaps in knowledge of health IT–related patient safety risks. These barriers to generating evidence pose unacceptable risks to safety.”

Despite the lack of definitive evidence, the committee said it “believes poor user-interface design, poor workflow, and complex data interfaces are threats to patient safety. Similarly, lack of system interoperability is a barrier to improving clinical decisions and patient safety, as it can limit data available for clinical decision making.”

The committee also argued that industry must play a greater role in making health IT safer. “When instances that either cause or could result in harm occur, there is no authority to collect, analyze, and disseminate learning. Lack of sufficient vendor action to build safer products, or regulatory requirements to do so, threatens patient safety.”

To redress that, the committee said the federal Department of Health and Human Services should somehow “ensure insofar as possible that health IT vendors support the free exchange of information about health IT experiences and issues and not prohibit sharing of such information, including details (e.g., screenshots) relating to patient safety.”

As well, the report recommends bolstered reporting and collection of data about health IT-related adverse events, such as deaths, injuries “or unsafe conditions.” Reporting should be mandatory for vendors but “voluntary, confidential, and nonpunitive” for users so as to ensure that doctors and other health IT users are not dissuaded from revealing adverse events because of liability concerns.

Other recommendations included a call on Health and Human Services to “publish an action and surveillance plan within 12 months that includes a schedule for working with the private sector to assess the impact of health IT on patient safety and minimizing the risk of its implementation and use,” as well as a call for the creation of a Health IT Safety Council “to evaluate criteria for assessing and monitoring the safe use of health IT and the use of health IT to enhance safety.” — Wayne Kondro, *CMAJ*

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