# Medically necessary: Who should decide?

A decision as to whether something is or isn't necessary depends a whole lot on who's doing the deciding. A new opera house downtown? "Yes," says the music-loving arts community. "No," says the cash-strapped city council. A new 90-inch television? "Yes," says the sports-mad husband. "No," says the level-headed wife.

In health care, opinions about whether a particular service, test or procedure is "medically necessary" — and therefore covered by provincial health plans — can also vary widely. Equally divisive, in some quarters, are opinions about who should be involved in making that decision.

"Medical necessity should be determined between the patient and the health care provider," says Dr. Douglas Mark, president of the Coalition of Family Physicians and Specialists of Ontario. "It should not be the government making that decision."

According to Mark, the Ontario government is about to start "micromanaging" health care in the province. The government will now decide if certain services, such as providing an MRI (magnetic resonance imaging) for low back pain, are really necessary and worthy of reimbursement through public funds. Mark claims this could eventually affect many fields of medicine, including cardiology, neurology, anesthesiology and ophthalmology.

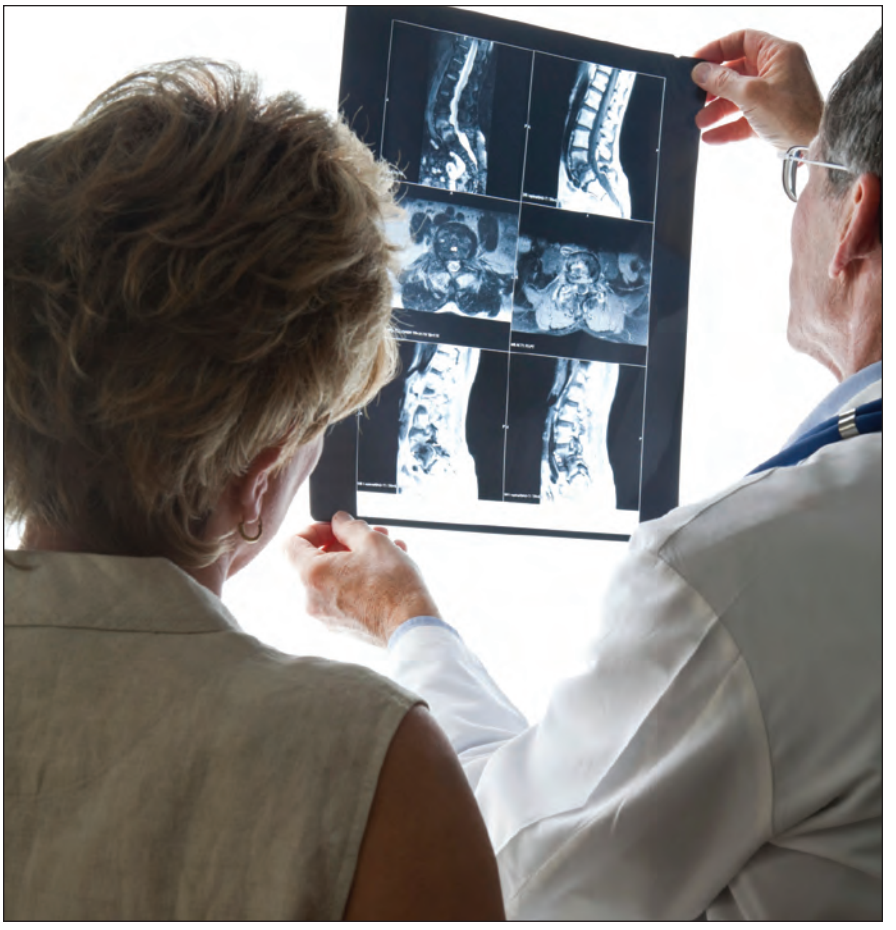
"Some nameless, faceless bureaucrat in the government will decide who is or is not eligible for coverage for these X-rays, CT [computed tomography], and MRI scans. Another example is mammograms," Mark stated in a press release (www.cofps.ca/2012/05/31/ontario-is-now-micromanaging-your-health-care). "Ultimately, it will be our patients who will have to pay for these tests themselves with their health or even their lives, despite having already paid for health care through taxes and the additional healthcare levy."

In response to government plans to revise the process for determining what's medically necessary, the coalition has issued a "call to arms" asking doctors to send an "Ontario Medically Necessary Authorisation Requestion Form" to the province (www.cofps.ca/wp-content/uploads/2012/05/Medically-Necessary-Authorisation-Requisition-Form1.pdf). It states that a patient is "waiting in office/clinic/hospital for your immediate reply" regarding his eligibility for at least one of a number of tests, including electrocardiogram, mammogram, ocular ultrasound, cataract surgery sedation, x-ray of the lumbar spine and electroencephalogram.

"It's ludicrous. They're the ones now making decisions, from the top down," says Mark. "It's completely backwards."

The government takes issue with that proposition. The point of the increased scrutiny is not to undermine physicians, but rather to base spending decisions on evidence instead of the judgment of physicians alone, says Deb Matthews, Ontario's Minister of Health and Long-Term Care.

The government will rely on expert committees — comprising physicians, academics and other experts — to review scientific literature and determine when, and for whom, a test or procedure is actually necessary. "We want people to get the care they need, but we don't want people to go through unnecessary tests and we don't want to pay for it," says Matthews. "I really believe doctors want to do what's right for patients and for the system, and some might interpret this as





**Ontario doctors will no longer be reimbursed for magnetic resonance imaging scans for patients with low back pain if the government deems them unnecessary.**

a challenge to their autonomy, but we have to do what's right for patients and what's right for the health care system."

Evidence suggests, for instance, that physicians are far more likely to order a test if they own the machine needed to perform it, notes Matthews. There is also a tendency among some doctors to order expensive tests prematurely. "We do know that some physicians were sending people with lower back pain for MRIs before doing anything else," says Matthews.

Academics who have studied processes for determining what is medically necessary tend to agree that clinicians shouldn't be the only ones involved. Though medical expertise is of course required, the reality is that money comes into play as well. Every public dollar spent on health care, after all, is a dollar that can't be spent to provide other types of services to citizens. And nobody expects doctors to make decisions about patient care based on how it will affect, say, teachers' salaries.

"There really is a role for people other than doctors in the process," says Mark Stabile, director of the School of Public Policy and Governance and professor of economics and public policy at the Rotman School of Management of the University of Toronto in Ontario.

Efforts to contain costs don't necessarily detract from the quality of health care, Stabile says. In fact, more efficient care can sometimes be better care, even if physicians are reluctant to accept outside influence on how their practices should be run.

"Everybody would prefer to have nobody interfere with them, but there is some evidence, a lot of it from the United States, that when doctors are shown they can do a job better by making some adjustments, in the long run they are happier," says Stabile.

According to some observers, bringing a wider range of experts into the mix is long overdue. "Doctors have had the reins completely on deciding what is medically necessary and what is not, and that is increasingly going to have to come under scrutiny," says Colleen Flood, a law professor at the University of Toronto and a Canada Research Chair in Health Law and Policy. "It's beholden on governments, who are spending public money, to take a look. … The government obviously has to be involved in the sense that they set the budgets. Who else is going to represent the public interest if not them?"

Others who might be able to provide valuable input to the process include ethicists, scientists, public policy experts and philosophers, says Flood. Members of the public should also have a voice, though questions remain about how and when they should be involved.

"At what point, given the historical and political complexities inherent in medicare, could (and should) the public be involved?" Flood and colleagues have asked (www.law.utoronto.ca/sites/default/files/health_basket/docs/working5_inandout.pdf). "What role could public values have in determining what services are publicly funded and which are left to the private sector?"

Whoever is involved, it is important that the process not merely be a bureaucratic exercise in saving money, says Flood. It must be a fair, reasonable process based on evidence. Most often, a decision regarding a particular test or procedure is not about whether it should be publicly funded — full stop — but rather about who really needs it and when is it necessary.

"We have to do this sort of thing to manage the health system," says Flood. "Individual doctors might not like having their decisions scrutinized, but why not? If you are making good decisions, why would you care?" — Roger Collier, *CMAJ*

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# Medically necessary: How to decide?

Implementing a process for making a decision based on defining a concept that may be indefinable can — surprise, surprise — be rather complicated. Just ask those tasked with choosing which health services are "medically necessary." Yet, difficult as it may be, establishing a more explicit process for making that decision is viewed by many as a vital step in keeping Canada's health care system afloat.

And putting off the hard work required to establish such a process is probably a bad idea, considering that future advances in genetic medicine will only make the task more difficult, suggests Timothy Caulfield, a Canada Research Chair in Health Law and Policy at the University of Alberta in Edmonton.

"Being able to tailor therapies and treatments for individuals based on the personalized-medicine trend is going to complicate defining 'medically necessary' even more," says Caulfield.

Imagine, for instance, a physician informing Patient A that she is eligible for a particular therapy, then turning to Patient B, who has the same medical condition but isn't genetically predisposed to respond to the same treatment, and telling him that his provincial government will not cover the cost. This would likely go down as well as cod liver ice cream.

"It could in some ways be more precise, but it could become even messier," says Caulfield.

Of course, reluctance on the part of some health professionals to define certain terms — "minimal," "adequate" and "required," to cite but a few ambiguous examples — should come as little surprise considering the many unsuccessful efforts to do so in the past. As for putting great effort into coming up with a tidy, all-encompassing definition of "medically necessary" — it's probably a waste of time, Caulfield has suggested (*Health Law J* 1996;4:63-85).

"There are those who believe a definition of this term, usually in the form of a list of services or as a basic benefits package, will provide a solution to certain health policy concerns. Both federal and provincial should resist pressure to adopt this approach," wrote Caulfield. "Given the history of the concept of 'medically necessary' and

the numerous failed attempts to define it, a practical, operational and meaningful definition is likely unattainable."

A more productive approach would be to create a framework — based on evidence, costs and benefits — to guide decisions about publicly funded health services, suggests Colleen Flood, a law professor at the University of Toronto in Ontario and a Canada Research Chair in Health Law and Policy. Other countries already do this, notes Flood, citing New Zealand and Israel. In Canada, provinces have largely left decisions about the medical necessity of health services to physicians — a very different approach than used to decide which pharmaceutical products are covered under provincial formularies.

"When it comes to drugs, you see more explicit decision-making being taken," says Flood.

A more technical means of weighing the costs and benefits of any given health service is warranted, Flood and colleagues have suggested, because it's well known that little evidence of effectiveness exists for many services routinely recommended by physicians (http://dspace.cigilibrary.org/jspui/bitstream/123456789/21334/1/What%20is%20In%20and%20Out%20of%20Medicare%20Who%20Decides.pdf?1).

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**Trade-offs are inevitable in any system with limited resources.**

Without a formal process to evaluate the effectiveness of a service before deciding to fund it, provinces will find it very challenging to later reverse course. "If you let a new service proliferate and everybody gets used to it, it is very difficult to take it away," says Flood.

Though physicians will always have to make the day-to-day decisions about medical care, there is still a role for higher level decision-making involving those familiar with nonmedical matters, such as provincial health budgets, notes Flood. You can't make the trade-offs inevitable in any system with limited resources, after all, if you don't know how much money is available. It is important, however, that the process not merely result in a rigid list, but that it also considers when a given service is appropriate and for whom.

"Just saying yes or no — full stop — isn't very helpful," says Flood. "What matters is that you have a fair process."

An important part of that process is determining which medical services should be delisted. These decisions are often unpopular, with both providers and partakers of delisted services, because it places emphasis on cost-effectiveness rather than only therapeutic value.

"The idea that this is only a medical decision, we have to let go of that," says Mark Stabile, director of the School of Public Policy and Governance and professor of economics and public policy at the Rotman School of Management at the University of Toronto. "We have to consider cost and effect."

In a study exploring the effects of delisting publicly funded medical services, Stabile and a colleague noted that resistance is to be expected (www.irpp.org/events/archive/nov05jdi/stabile.pdf). "Providers of those services will naturally be critical of the decision if they feel that the demand for their services will decline as a result of de-listings," states the paper. "In publicly funded systems, critics of privately financed health care systems will claim that any de-listing is the start of a 'decline' in publicly funded health care."

Still, it must be done if funding is to be made available for new, more-effective services. There are four important factors to consider when building a framework for assessing whether a medical service should be delisted, the paper suggests: If it provides not only medical value but also "a benefit per unit of cost that exceeds the next best alternative;" how delisting will affect demand; how changes in health outcomes due to delisting compare to the benefits gained by the money saved; and if delisting will disproportionately affect particular groups of people.

"Overall, our results suggest that policy makers should be aware that the demand response differs significantly by service and by individual characteristics," the paper concludes. "This information should be considered as services are considered for (continued) public funding."

Plans to implement a more explicit decision-making process to determine which medical services should be publicly funded have been put forward by at least one Canadian province. Ontario will be forming expert committees, comprised of practitioners and academics, to determine the medical necessity of certain services, such as magnetic resonance imaging for low back pain.

"I have made it very clear that we are going to be increasingly relying on evidence about what we will fund and what we won't fund," says Deb Matthews, Ontario's Minister of Health and Long-Term Care. "Our health care dollars are very precious. I don't want to spend those dollars on things that don't improve patient outcomes."

But the notion that a bureaucratic process can deem whether a medical service is necessary has been met with accusations of micromanagement from the Coalition of Family Physicians and Specialists of Ontario. Instead, the process should remain as it has been — a discussion between a patient and a doctor, according to coalition president Dr. Douglas Mark. "It has to be individualized," says Mark. "The worst thing is putting them [the government] between us and the patient in making that decision." — Roger Collier, *CMAJ*

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# Needling toward essential health benefits

The era of acupuncture's existence as a practice on the margins of medicine appears to be inexorably drawing to a close.

Moves are afoot in California and Maryland to include acupuncture as an essential health service covered by insurance plans, while several other states have launched themselves along a similar trajectory.

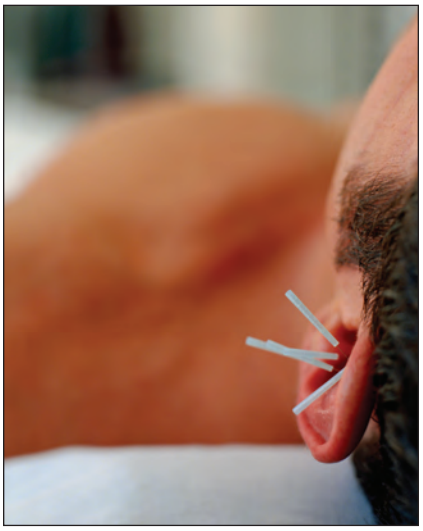
In Canada, meanwhile, British Columbia has already made acupuncture a medically necessary service covered by its health care plan, while four other provinces are now regulating the practice. Canadian practitioners hope this is the first step toward acupuncture's inclusion in their provincial health plans, primarily as a treatment for pain and postoperative nausea, although they acknowledge that it may be some time coming.

The moves in California and Maryland are being undertaken under the rubric of reforms prompted by the federal Patient Protection and Affordable Care Act, the legislative foundation of United States President Barack Obama's overhaul of the American health care system. It requires all states to create "Affordable Insurance Exchanges" under which individuals and small businesses can buy basic health coverage.

To that end, states had to choose, before Sept. 20, a "benchmark" health plan that exchanges must meet or exceed. It had to offer a basket of health services in 10 areas, including chronic disease management, emergency services, maternity and newborn care, mental health and substance abuse services, prescription drugs, ambulatory care and rehabilitative care. Exchanges must adopt the essential health benefits specified by the benchmark by January 2014.

In California, two different bills designating acupuncture as an essential health serviced now await Governor Jerry Brown's signature. If, as expected, he signs those bills into law, "it would guarantee at least a nominal level of access to acupuncture care" for almost all Californians, says Bill Mosca, executive director of the California State Oriental Medicine Association.

In Maryland, the benchmark plan was to be chosen from among six existing health insurance plans now offered to residents of the state, all of which contain acupuncture benefits. "Acupuncture will definitely be included — our state feels it meets the criteria for ambulatory services under the designations for EHB [essential health benefits]," Tracy Soltesz, president of the Maryland Acupuncture Society Inc., writes in an email.





**Acupuncture is often used as a treatment for pain and postoperative nausea.**

The lobby to declare acupuncture an essential health service has been fierce, and nationwide. The American Association of Acupuncture and Oriental Medicine has focused its efforts on the United States Department of Health and Human Services, while the association's member organizations have targeted state legislators.

"Every state is working on it," says Michael Jabbour, a New York acupuncturist and president of the association, which contends that acupuncture is a more effective, less costly and less invasive procedure than many surgical and pharmaceutical options. Their position is bolstered by a recent meta-analysis which concluded that acupuncture worked better than standard treatment or placebo to relieve pain from chronic headaches, backaches and arthritis (http://archinte.jamanetwork.com/article.aspx?articleid=1357513).

In Canada, only BC reimburses acupuncture treatments under its provincial health insurance plan. While both physicians and non-physicians can practise as acupuncturists in Canada, only BC, Newfoundland and Labrador, Alberta, Quebec and Ontario regulate the profession.

Although most provinces are rushing to de-list rather than add services to their provincial health plans, complementary medical services such as acupuncture should be included on those lists if the evidence supports their use, according to experts like David Moher, a senior scientist at the Ottawa Hospital Research Institute in Ontario. "I don't think we should treat complementary medicine different than drugs, he says, adding that the benefit to patients should dictate coverage. "Drugs are not without harm and I'm really interested in what's out there for patients and consumers more generally," he says.

Canadian acupuncturists, though, do not appear to be pursuing inclusion as aggressively as their American counterparts. For example, while the College and Association of Acupuncturists of Alberta began regulating its profession last year, it has not yet sought coverage in the provincial insurance plan, says Registrar Paul Hu.

But if the provincial government "would provide even limited coverage for acupuncture services, that would be good. We would like it if in the future it would be covered by Alberta Health Services," he adds.

Historically, there has been animosity between medical and nonmedical practitioners over the use of acupuncture, says Dr. Linda Rapson, a physician who uses the alternative therapy at her pain clinic in Toronto, Ontario. But an increasing number of Canadians are turning to such therapies to treat chronic conditions and an increasing number of physicians are willing to refer patients for such treatment, she says.

"Rather than acupuncture being a last resort, if it were used more liberally, it would certainly put a dent in our health care budget in Canada," says Rapson, who is also executive president of the Acupuncture Foundation of Canada Institute. — Laura Eggertson, *CMAJ*

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