International panel says CIHR needs management overhaul

Published at www.cmaj.ca on Sept. 12, 2006.

Never let it be said that Canadian Institutes of Health Research (CIHR) President Dr. Alan Bernstein lacks nerve.

Few, if any, heads of scientific granting councils around the world would subject their agency's structure, functions and processes to the scrutiny of international peer review, as Bernstein did by asking a 27-member high-powered panel chaired by Oxford University Regius Professor of Medicine Dr. John Bell to peek under CIHR rocks.

Bernstein admits that midway through the process he gazed around the room, saw the intellectual firepower training its guns on his 5-year-old agency and asked himself: "What have I done here?"

Given the verdict, he's probably still shaking his head, as the International Review Panel (IRP) pulled few punches in its final report.

Overall, the science is fine, although it's premature to legitimately judge the success of the great experiment, i.e., dissolving the old Medical Research Council and recreating from its ashes a new agency featuring multidisciplinary "virtual" health research institutes that vastly expand the ambit of Canadian research beyond basic biomedical science to include 3 other pillars: clinical, population health, and health services and systems research.

But many CIHR operations are overly complex, if not downright incoherent and chaotic, the IRP states in its final report. Peer review panels are fatigued, while there are so many strategic initiatives it's arguable whether any are actually strategic priorities.

Even the CIHR's governing council was taken to task, in need of having its wings clipped and more "clarity" with regard to its responsibilities.

Canapress

CIHR President Dr. Alan Bernstein says the agency may devolve some of its decision-making authority.

"New structures need now to be imbedded, transparency in decision-making and process is crucial and sound governance becomes increasingly important. We believe that this represents a natural progression in the growth of this new entity but nevertheless a crucial one for the long-term viability of the organization."

When the CIHR was formally created in 2001, proponents argued expansion of its mandate to 4 pillars was justification for a major funding increase. Its core budget has since risen from about $250 million a year to a current level of $717 million. It also administers another $111 million in flow-through monies under the Canada Research Chairs and Networks of Centres of Excellence programs, leaving the CIHR in charge of a whopping $828 million.

The agency's structure was a careful compromise. Unlike the US, where the National Institutes of Health individually administer enormous pots of money for both intramural and extramural research, the bulk of Canadian operating grants would continue to be centrally administered, while the CIHR's 13 virtual institutes would oversee more modest pots for strategic initiatives. The compromise gave the governing council the means to ensure that the basic, biomedical community wouldn't simply gobble up budget increases and that the agency would indeed significantly expand research in the other pillars, as well as invest more in multidisciplinary research and promote interdisciplinary collaboration in areas of national health need.

In many respects, the IRP recommendations can be viewed as a call for limitations on that expansion. Among recommended measures are ones that would give the CIHR's 13 institutes, and their scientific directors, authority over all grants that are issued under their respective themes (such as neurosciences or cancer). Even competitions for basic, investigator-initiated operating grants would fall under Institute administration.

The pie would be divided by a "research committee" comprised primarily of Institute scientific directors, thus pro-

viding more of what the IRP called "academic leadership." The IRP argued the committee should be handed oversight of all CIHR funding, including determining a suitable balance between investigator-initiated and strategic initiatives for each discipline. The risk in such an approach, of course, is that larger, more biomedical disciplines, like neurosciences, might gobble up a larger chunk of available monies, at the expense of smaller disciplines in the other 3 pillars. There'd also be less incentive to pursue multidisciplinary and interdisciplinary research, and fewer mechanisms and programs to promote such research.

Bernstein declined to discuss the recommendations in any detail, saying that although the governing council discussed them at a late August retreat, no decisions have been taken. Moreover, the CIHR wants to undertake extensive consultation with the research community before making changes.

Broadly speaking, though, Bernstein said it may be timely for CIHR to devolve some of its decision-making authority. "How I read that is [the IRP] wanted to have more transparency and clarity as to how overall decisions are made and suggested one way to do that would be to devolve down to what they called this research committee."

But governing council felt they needed "more time, and more input from scientific interests and the broader community" before agreeing to limit its powers, Bernstein added. "But clearly, if they're going to devolve more, we need to look at the structures underneath."

The IRP also took the CIHR to task for its plethora of strategic programs and the impact those have on peer review. "We were told that researchers are now suffering from significant review fatigue. Ensuring that panels are supplied with high quality and senior scientists is apparently proving difficult and the changing of panels due to potential conflicts of interest makes these problems even more difficult. The small size and short duration of some grants, the establishment of a large number of new grants committees and the presence of committees that see few proposals suggests that the peer review system is not being optimally managed. There appears to be no open and transparent process for the establishment of new panels. Nor does there appear to be clear criteria or process for their evaluation and, in the event that a particular panel is no longer needed, how this decision is to be reached. There have many been new panels established and none eliminated in the past 6 years."

> In many respects, the recommendations can be viewed as a call for limitations on CIHR's expansion.

Yet, it's difficult to imagine an argument that would generate less political sympathy than complaints from the scientific community about the trials and administrative tribulations of having to administer ever larger pots of taxpayer dollars, for both basic and strategic research.

Bernstein carefully sought middle ground.

The scientific community, he said, greatly appreciates that the federal government has in recent years trusted the CIHR (and therein, the academic community) to administer new pots of money, like ones for HIV/AIDS, the flu pandemic and cancer. "It expresses a confidence on government's part that the CIHR is capable and will respond to the country's strategic needs."

Still, a tighter leash on strategic programming may be warranted, Bernstein said, adding the future may see fewer strategic grants awarded, at a higher level. To that end, CIHR has already done some trimming. "If you look at the last of our RFAs [request for applications] that came out in June, there's fewer of them, considerably fewer, about 20% fewer."

As for the strain on peer reviewers that's caused by the explosive growth in public spending on health research, Bernstein was quick to dispel any notion that the solution is to cut funding, arguing that far more productive solutions can be found by either promoting more interagency peer review and by convincing "more senior people in the scientific community in Canada that they should be part of the review process. They can't be above it."

In response to the IRP's assertions that governing council needs to clarify its roles and responsibilities by becoming more of an advisory committee, rather than "a committee with executive functions or as a main Board of the CIHR," Bernstein said council isn't adverse to a less hands-on approach. "It has no difficulty accepting the notion that council should be more involved in policy and strategic direction. But they did not want to become aloof, in the sense of meeting in a perfunctory way and just looking at the books and making sure they were balanced every year."—Wayne Kondro, *CMAJ*

DOI:10.1503/cmaj.061162

Ibuprofen redux

The news article "Ibuprofen should go behind-the-counter says expert panel" (*CMAJ* 2006; 175[3]:253-4) requires further elaboration of Health Canada's position on this issue. Health Canada started its internal scientific review on the safety of long-term use of COX-2 more than 6 months before convening an Expert Advisory Panel on the Safety of COX-2 Selective Non-steroidal Anti-Inflammatory Drugs. The Health Canada review did not initially specifically look at the safety of ibuprofen. However, according to Dr. Marc Berthiaume, director of the Marketed Pharmaceuticals and Medical Devices Bureau: "Health Canada has since studied the available safety data on ibuprofen and has found no evidence of increased cardiovascular risk when the product is used over-the-counter as directed, i.e. for short-term and at low-dose [200-400 mg].

However, Health Canada acknowledges that increased cardiovascular risk may be associated with high-dose ibuprofen, as with COX-2-selective and other "non-selective" NSAIDs. Berthiaume added: "Patients have the responsibility to use as directed any nonprescription or prescription drug, and ibuprofen is no exception." In general, he says there is a need for more long-term comparative studies to further characterize cardiovascular safety concerns surrounding NSAID drugs including ibuprofen and COX-2. — Barbara Sibbald, *CMAJ*

DOI:10.1503/cmaj.061163

Injection site gets 16-month extension

As summer ran its course in Vancouver, a 3-year experiment to provide heroin addicts with a medically supervised injection site neared its scheduled Sept. 12 expiration. Canada's former Liberal government had granted the facility, InSite, a permit exempting it from federal drug laws. To remain open, InSite required a new permit from the Conservative government — some of whose members argued it's morally wrong to aid illegal drug addiction.

InSite is in the Downtown Eastside, Vancouver's impoverished neighbourhood of concentrated HIV and hepatitis sufferers, drug addicts and dealers, sex-trade workers and criminals. North America's first and only such site, it daily serves about 600 addicts who bring in illegal street drugs and then inject themselves with syringes dispensed by InSite, under the watch of health professionals. Nurses and doctors intervene if users overdose and offer general health care, while counselors are present to offer addiction treatment.

Some 50 similar sites exist worldwide, but InSite remains audacious given the US "War on Drugs" next door. In British Columbia, however, it has massive public and political support under a popular "Four Pillars" drug strategy of prevention, enforcement, harm reduction and treatment.

During InSite's 3 years, a remarkable consensus that the facility reduces harm to users and the public developed among scientists, criminologists and even the Vancouver Police Department. Research, all positive, was published in 15 peer-reviewed journals, including the *CMAJ* (2004;171:731-4), *Lancet* (2005; 366:316-8) and the *New England Journal of Medicine* (2006;354:2512-4).

In the spring of 2006, the province wrote to Ottawa formally applying for a 3.5-year renewal of InSite's permit.

Ottawa's response was a long silence.

Over the summer, InSite became a *cause célèbre*. Activists, politicians and even scientists lobbied for it, and at the international AIDS conference in Toronto researchers spoke in support while AIDS activists demonstrated in the streets. Lawsuits were threatened. Ethicists joined the fray, including Margaret Somerville of McGill University's Centre for Medicine, Ethics and Law, who said given that addicts would continue to be addicts, reduction of serious harms such as HIV and hepatitis infection is an ethical requirement. One of the few opponents was the Canadian Police Association, which in late August demanded that Ottawa close InSite and focus instead on a national drug strategy.

Less than 2 weeks before InSite's scheduled closure, on Sept. 1, federal Health Minister Tony Clement announced he was deferring a decision on InSite pending more research, but it could remain open until Dec. 31, 2007. Clement's announcement asked: "Do safe injection sites contribute to lowering drug use and fighting addiction? ... Right now the only thing the research to date has proven conclusively is drug addicts need more help to get off drugs."

The Canadian HIV/AIDS Legal Network accused the government of "playing politics with people's lives."

Dr. Evan Wood, an epidemiologist at the BC Centre for Excellence and HIV/AIDS and assistant professor of medicine at University of BC who is, with Dr. Thomas Kerr, principal investigator for evaluation of InSite, argues that science clearly shows the benefits of InSite, and seemed nonplussed to find himself one of InSite's most vehement backers.

"I am a scientist, and I hate to be referred to as an advocate," he said. "But Dr. Kerr and I ... want to see the problem improved as scientists, because the benefits have been so positive."

Wood added, "I felt like the federal government was politicizing this because the science is that strong." — Deborah Jones, Vancouver

DOI:10.1503/cmaj.061209

Canapress, F. Gunn

Activists protested the imminent closure of InSite at the 16th World AIDS Conference held in Toronto this August.

Hepatitis E and cholera outbreak in Kathmandu

The incidence of infective diarrhea and hepatitis E has sharply increased in Kathmandu, Nepal, said doctors at a recent press conference organized by Liver Foundation Nepal.

This summer, the Epidemiology and Disease Control Division (EDCD) of Nepal received notification of 55 cases of cholera from the capital alone. In addition, this is the fourth outbreak of hepatitis E in recent years in Kathmandu, and the largest so far.

Dr. Santosh Man Shrestha, president of Liver Foundation Nepal said, "Recurrence of liver disease in a particular area is rare in other parts of the world but this is the fourth Hepatitis E outbreak in Kathmandu Valley."

Hepatitis E and diarrheal diseases are an important public health concern in Nepal. Diarrheal diseases are the second largest killer of children here; 10 million children suffer from diarrheal disease every year and about 28 000 of them die.

"We suspect drinking water as the source of contamination behind these outbreaks but we have not received any official report of drinking water tests from the Nepal Water Supply Corporation, which has the responsibility of testing water quality," said Dr. Manas Kumar Banerjee, EDCD director.

The water supply infrastructure of Kathmandu Valley is very old. There are many leakages, and the drinking water is easily contaminated by the sewage and other substances from the sanitation pipes.

"Besides lack of safe drinking water, feeding children without first washing hands properly, using dirty utensils to carry water, eating dirty and stale food are other causes behind an increase in these infectious diseases." says Banerjee.

EDCD has recently incorporated diarrheal diseases in its priority and has increased its surveillance. In addition, the Nepal Water Supply Corporation has started chlorinating drinking water.

"Disinfecting water certainly helps contain outbreaks on a short term. But only through provision of pure water and increase in the awareness level of people about the importance of good hygiene can future outbreak of these diseases be stopped," says Banerjee. — Dr. Sharan Prakash Sharma, Kathmandu, Nepal

Art Explosion

Aging water supply infrastructure is a public health concern in Kathmandu.

DOI:10.1503/cmaj.061166

Schwarzenegger vetoes single-payer bill

California Governor Arnold Schwarzenegger has promised to veto a government- financed single-payer universal health insurance bill passed by the state legislature claiming "socialized medicine is not the solution to our state's health care problems." He emphasized that such a measure would "cost the state billions and lead to significant new taxes ... without solving the critical issue of affordability."

Bill SB 840, written by Democratic State Senator Sheila Kuehl, was supported by various health access coalitions and labour groups but was seen by many political analysts and media commentators as a political ploy by the Democrat-controlled legislature to paint the governor into an "anti-health" position in run-up to the November elections.

The bill would have replaced the network of public and private insurance programs that currently cover the great majority of Californians with a state-financed and administered health system. Except for federally funded Medicare (for the elderly) and Medicaid (for the poor), most health insurance in California, as throughout the US, is funded by employer plans. SB 840 would have covered medical, dental, vision, hospital services and prescription drugs, and would have been funded through payroll and individual income taxes and premiums. Currently, approximately 6 million Californians are uninsured for health care.

In explaining his veto, Schwarzenegger said he "must veto" the bill "because I cannot support a government-run health care system."

"I won't jeopardize the economy of our state for such a purpose," he added in a statement.

Kuehl countered that, "Where there are no cost controls at all now, and enormous administrative overhead and profit for insurance companies, there would have been a transparent system that actually would succeed in making health care coverage affordable in California."

Leading the condemnation of Schwarzenegger's veto, Deborah Burger, president of the California Nurses Association, said the governor was "abandoning millions of Californians to health insecurity and potential financial ruin from un-payable medical bills."

Critics of SB 840 say that the bill itself was fatally flawed because it did not include cost projections or information about who would pay and what premiums would be required.

Another sign of the bill's weakness was that although it was passed handily by the Democratic-controlled State legislature (Schwarzenegger is a Republican), it was not supported by Phil Angelides, the Democratic candidate for governor in the November election. Though Angelides says he favours some form of universal health insurance, he has not backed the current version.

According to a recent Public Policy Institute of California poll, the veto is not likely to seriously hurt the incumbent in November. Less than 4% of respondents to a statewide poll cited health insurance coverage as the main issue in the November election. — Milan Korcok, Ft. Lauderdale, Florida

DOI:10.1503/cmaj.061200

Quebec specialist taking government to court

When obstetrician-gynecologist Deborah Robertson decided to pursue training in advanced surgery in Toronto, she never dreamed she might be leaving her home province of Quebec for good.

"I love working in Quebec," says Robertson. "But for me, Bill 37 has been quite discouraging: It's forced me to change my plans."

Bill 37, adopted by the Quebec legislation on June 13, imposed a wage settlement and working conditions on medical specialists until 2010.

On Sept. 12, the Quebec Federation of Medical Specialists announced it will take the Charest government to court to contest the law's validity under the Quebec and Canadian charters of rights.

Under the imposed contract, Quebec's 8000 medical specialists receive a 2% wage increase in each of 4 years, leaving them on the bottom rung of the Canadian specialists' salary scale. The average gross annual income for a specialist in Quebec is $233 000 — $100 000 less than the national average.

The specialists' federation says the monetary package is disappointing, but it's what the federation calls the "extraordinary and punishing" nature of the decree that has pushed it to challenge the law's constitutionality.

"It is an abuse of power and a breach of doctors' rights to freedom of association and freedom of expression," says Dr. Yves Dugré, the federation's president.

Bill 37 penalizes Quebec specialists for failing to accept a $593-million global offer in early June. The imposed contract cut $125 million from that offer and docked a further $50 million from the deal in fines and penalties. There is also a threat of further penalties should specialists balk or do anything to protest against their working conditions or wages. These penalties include not renumerating specialists for the time during which they contravened the act, plus a fine of double what they would have been paid, up to 20% of their total pay.

"We are handcuffed," says Dugré. The law imposes heavy fines for any kind of "concerted action," which the federation's legal expert, Sylvain Bellevance, interprets as anything from modifying work practices to quitting or accepting a position in another province.

"You're not allowed to resign," Bellevance says. "It's absurd. A doctor and his wife decide to go practise in Ontario — they can't. There is no limit to this law."

CMA's general council unanimously passed (with one abstention) a resolution in August, urging the association and its divisions to "staunchly oppose any form of coercive legislation in regard to the negotiation of working conditions and compensation of physicians."

Quebec Health Minister Philippe Couillard — a retired neurosurgeon — says the specialists' interpretation of Bill 37 is "grossly exaggerated."

"We want to prevent any mass desertion from our hospitals." Couillard says. "But there's nothing in the law that prevents people from discussing it." He called the legal challenge "unfortunate," suggesting it could stand in the way of productive talks between the government and Quebec doctors.

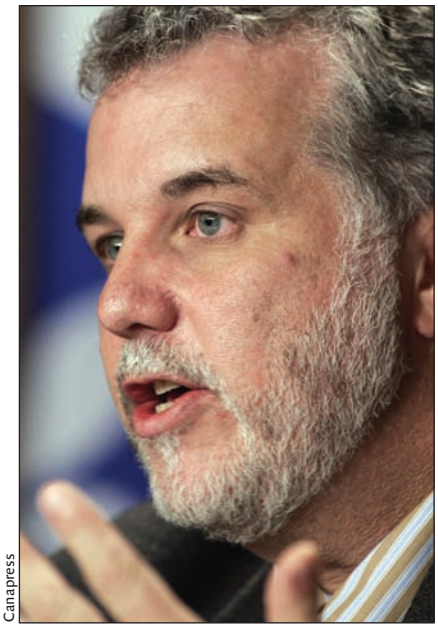
Dugré contends Bill 37 has deepened a climate of resentment among Quebec doctors, who are considering pulling up stakes in ever greater numbers.

A survey conducted by Leger Marketing for the Quebec Medical Association in August shows that 23% of physician respondents are considering leaving the province in the next 5 years. That figure climbed to 29% among medical specialists, and 39% among young doctors (those who have been practising 10 years or less).

Almost all (94%) of the doctors say Bill 37 is fully or partly responsible for hurting morale and motivating them to look elsewhere for work.

Even among family doctors — who accepted a final offer from the government in June and thus are exempt from the special law — frustration is growing. In the same survey, 88% expressed dissatisfaction with their salary level. Like Quebec specialists, their wages are the lowest among their peers across Canada.

The Quebec government has deferred until 2008 a promise made 3 years ago to close the gap in salaries between Quebec doctors and those in the rest of Canada. The specialists' group is also challenging that delay. It has filed a complaint with Quebec's Arbitration Council, to oblige the government to observe its 2003 commitment to reach wage parity, or to pay damages and interest for failing to do so.



Canapress

Quebec Health Minister Dr. Philippe Couillard says the door is still open to discussing wage parity.

For his part, Health Minister Couillard says the door is still open to continue talks toward wage parity. "It's not because the government doesn't value their work that doctors are paid less in Quebec," says Couillard. "The question is where will the money come from? Are we going to cut home care to give more money to physicians?"

Couillard has not indicated any willingness to rescind Bill 37 — and specialists say that reluctance to rethink the government's position is bound to lead to a worsening physician shortage.

Until Bill 37 is "off the table," Robertson says that she's staying put right where she is, in Toronto. — Loreen Pindera, Montréal

Loreen Pindera is a journalist with CBC Radio in Montréal.

DOI:10.1503/cmaj.061210

Plan B available to women 18 and older in US

The US Food and Drug Administration has approved over-the-counter use of levonorgestrel (Plan B), the morning-after emergency contraception pill, to women who can prove they are 18 or older.

OTC sales of levonorgestrel, which has been available by prescription since 1999, are anticipated before the end of the year nationally. The 2-pill pack costs from US$25 to $40. Nine states, Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Washington and Vermont, already allow women of any age to buy levonorgestrel OTC from designated pharmacies.

According to the FDA approval announcement on Aug. 25, girls 17 and younger will still need a doctor's prescription (except in those states that specifically allow access at any age).

Levonorgestrel has been available OTC in Canada since April 2005 (*CMAJ* 2005;172[7]:86-7). Unlike Canada, US pharmacists will not provide counselling services when they sell the product.

The US approval caps a stormy 3-year debate in which medical organizations and women's rights groups argued that OTC status for levonorgestrel could cut the nation's annual 3 million unplanned pregnancies in half. Social conservative groups feared easier access for younger women would encourage promiscuity and increase sexually transmitted disease. Many also argued that imposing the 18-year-old limitation would be as ineffective as similar limitations on cigarettes and could be easily circumvented by 18 year olds buying the drugs for younger friends.

In applauding the FDA action, American Medical Association Board member Dr. Joseph M. Heyman said "Plan B meets all of the customary criteria for OTC availability. This classification of the drug will increase women's access to emergency contraception and can prevent unwanted pregnancies."

The American College of Obstetricians and Gynecologists (ACOG) also approved the action but faulted FDA on limiting the drug's access to women 18 or older. In a statement, ACOG noted: "By restricting its OTC availability to women age 18 and older, the FDA has missed an unparalleled opportunity to prevent teenage pregnancies. Each year there are more than 800 000 teen pregnancies in the US, with many ending in abortion. Pregnancy itself is not without risk, especially for a young woman."

Drug manufacturer Barr Pharmaceuticals notes that levonorgestrel should be taken within 72 hours of unprotected sex, but that the sooner it is taken the more effective it will be. Barr says that if taken within 72 hours, levonorgestrel can reduce the risk of pregnancy by 89%. — Milan Korcok, Ft. Lauderdale, Florida

DOI:10.1503/cmaj.061164

News @ a glance

Birth rates: Canada's crude birth rate declined to a record low in 2004, with just 10.5 live births for every 1000 people, according to Statistics Canada's annual projection. It marked the second straight decrease in the number of live births, from a 10.6 rate in 2003. The statistics also indicate a continuation of a long-term trend toward giving birth later in life; in 2003, the average woman was 29.6 years old, in 2004, the average was 29.7. Births to mothers aged 35 and older are now almost 4 times as frequent as they were a generation ago, accounting for 17.2% of births in 2004, as opposed to 4.6% a quarter century earlier.

Comstock

Head injuries: Although seatbelts and helmets appear to have helped reduce hospital admissions due to traumatic head injury over the last decade, particularly among youths, under age 19, and people over 60, people in these age groups remain at greatest risk of requiring head injury hospitalization because of falls, motor vehicle crashes or recreational mishaps, according to a new Canadian Institute for Health Information report (www.cihi.ca). Overall, 35% fewer Canadians were admitted to hospital for head injury in 2003–2004 (16 811), as compared to 25 665 in 1994–95. But Canadians under age 19 still account for 30% of all head injury hospitalizations, followed by 29% among those 60 and older. Falls (45%) are the leading cause of traumatic head injury, followed by motor vehicle incidents (36%), assault (9%), and sports and recreational activities (8%). Falls and sports activities cause more hospitalizations among youths and seniors, while motor vehicle crashes, assault and homicide play a greater role in hospitalizations among those aged 20–39.

Go North: The Yukon government is offering eligible new family physicians up to $50 000 to practise in the territory. The Family Physician Incentive Program for New Graduates, part of the territory's $12.7-million health human resources strategies, will give eligible candidates $20 000 when they move, $20 000 after two years and $10 000 at the end of the fourth year.

Youth and tobacco: The number of youths (grades 5 through 9) trying tobacco products decreased by 50% between 1994 and 2004–05. Health Canada's *2004–05 Youth Smoking Survey* reports that 21% of youths have experimented with these products (cigarettes, cigars or pipes, bidis, chewing tobacco and snuff). Cigarettes was the most common product tried (19%). Two percent reported being smokers, compared with 7% in 1994. In contrast, 63% of youths had tried alcohol, compared with 54% in 2002. — Compiled by Barbara Sibbald, *CMAJ*

DOI:10.1503/cmaj.061178