impact of drugs on patients. "Governments have walked away from drug development and left this to the commercial sector," he said. But by promoting data linkage and drug safety, governments can re-engage.

The former regulator acknowledged that changes to regulations take time, often several years. In the interim, he suggested that insurance companies or employers could make decisions about the conditions under which they would cover drug costs, addressing for example the off-label use of a drug.

Peterson worked for the changes he now advocates during his 5-year tenure at Health Canada. It was not frustration with the pace of change that led to his departure, he said. "But I also knew there were issues with a minority government and another election coming that might delay some of these changes." His decision to leave was also prompted by consideration of what he wanted to do with the remainder of his career.

Peterson continues his involvement with regulatory matters as chair of the regulatory advisory board of the UK-based Centre for Medicines Research International, he said. He is also a member of the Canadian Expert Drug Advisory Committee, which provides advice to the Common Drug Review. — Ann Silversides, Toronto

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Alberta leads country in e-health records

Talking to Dr. Tim Kolotyluk about cybermedicine is like running beside a freight train. You can't keep pace with his enthusiasm.

Kolotyluk, a 53-year-old family doctor in Westlock, just north of Edmonton, wired his clinic in 1998 knowing electronic health records were the way of the future. Today, Kolotyluk is one of 2899 Alberta physicians who have benefited from the Physician Office System Program (POSP), a government incentive to encourage office automation.

Kolotyluk and his 3 clinic colleagues have computers and printers in every examination room, 2 servers, voice recognition software, an information technology expert on call and a staff freed of paper files.

"You can no longer say, 'I don't like computers.' Our patients are leading the way with questions about the Internet," says Kolotyluk. "They have said, 'Come along with us.'"

The 5-year-old incentive program, which has cost taxpayers about $70 million so far, offers physicians up to $35 520 in monthly installments over 4 years, a sum intended to cover 70% of the cost of hardware, software and networking. Physicians are expected to pay the remaining 30%.

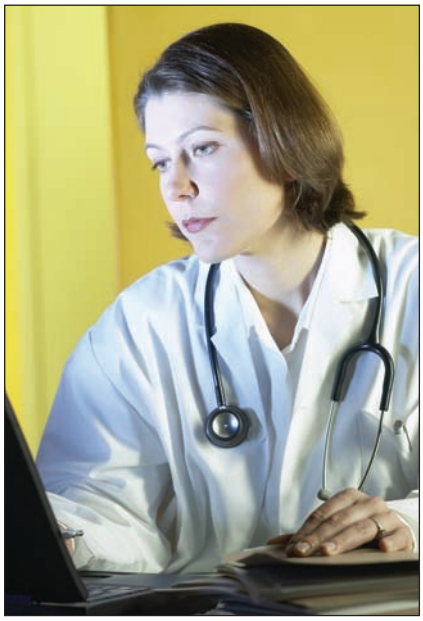
Roughly 53% of practising physicians have incorporated information technology into their practice in Alberta, the highest rate in Canada. Of those, more than 80% are currently using or converting to electronic medical records.

The Alberta Medical Association maintains doctors gave up about 1.5% in fee increases during contract talks in 2001 to designate money to the program. They could perhaps afford the sacrifice: Alberta physicians negotiated a 22% increase over 2 years in 2001, making them some of the highest paid medical professionals in the country at the time.

Oil-rich Alberta may have more discretionary spending than most provinces, but proponents say it's the innovative structure of the program, not just the dollars, that won converts — a structure they say required insightful leadership and compromise from physicians, government officials and, later, the health regions.

Dr. Fraser Armstrong, an Edmonton physician and co-chair of the AMA's POSP committee, explained the program's cornerstones:

- Vendor Conformance and Usability Requirements: a set of technical requirements against which technology vendors' products are conformance tested. Physicians must choose products that are VCUR-certified in order to get funding.
- Change management: The program provides management services through a network of private sector resources and physician mentors dedicated to helping physicians convert from paper to electronic records.
- Privacy Impact Assessment: Physicians are required to submit an assessment to the province's Information and Privacy Commissioner outlining how they plan to protect patient information.



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Roughly half of practising physicians have incorporated information technology into their practice in Alberta.

Armstrong is excited about the seemingly limitless opportunities computer technology affords doctors and patients: diagnostic tools that flag patient files for things like drug interactions, allergies and mammograms; efficient transfer of lab results and patient hospital reports; and easy access to complete patient files for clinic colleagues.

"I think we're stepping to a new level," he says. "We'll look at the patient differently than we ever have — more comprehensively."

The program has created a national buzz, especially in provinces struggling to establish electronic record-keeping. "Alberta has the best program I've seen and I've looked into the United States as well," says Bill Pascal, the Canadian Medical Association's chief technology

officer. No province, no matter how financially challenged, can afford to ignore cybermedicine, he says. Electronic records save government money in the long run and help doctors deliver better, more comprehensive care.

Mark Dermer, senior medical advisor for Canada Health Infoway, calls the program revolutionary and groundbreaking. "It was the first time a jurisdiction recognized the need for financial assistance to physicians working in private offices," he says. Expecting physicians to pay for equipment, support and transition is "fundamentally unfair."

Infoway, a not-for-profit agency comprised of Canada's provincial and territorial deputy health ministers, promotes the use of efficient health information systems by funding innovative projects, end-user education and by establishing national, inter-operability standards.

While the Alberta government, the AMA and the health regions hammer out the next phase of the program, which could extend funding to 2008, policymakers continue to debate larger questions of overall system security, patient confidentiality and database usage. Electronic medical records offer a plethora of research possibilities and just as many potential controversies. For now, secondary use of that database is considered off limits. — Lisa Gregoire, Edmonton

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Dispute over Vioxx study plays out in New England journal

The *New England Journal of Medicine* is maintaining that a Canadian-led study of the anti-arthritis drug rofecoxib (Vioxx) that it published in November 2000 contained "misleading" conclusions regarding the drug's safety.

But the authors of the Vioxx Gastrointestinal Outcomes Research (VIGOR) clinical trial, led by Dr. Claire Bombardier, a University of Toronto rheumatologist, insist they followed the rules and their conclusions weren't compromised.

The controversy over the study's results played out on the pages of the *NEJM*'s March 16 edition. The issue contained an editorial reaffirming the journal's December 8th 'Expression of Concern' about the original study, as well as a defence advanced by Bombardier and 10 other non-Merck authors (*N Engl J Med* 2006;354:1193, 1196-9).

The *NEJM*'s editors allege results from the VIGOR study (*N Engl J Med* 2000;343:1520-8) were skewed because the authors, when submitting their paper for publication, withheld clinical trial data about 3 myocardial infarctions suffered by subjects taking Vioxx. "Because these data were not included in the published article, conclusions regarding the safety of rofecoxib were misleading," the journal said. The editorial cited documents filed in US courts that revealed at least 2 of the authors were aware of the additional heart attacks at the time they submitted their paper.

Upwards of 10 000 lawsuits have since been filed against manufacturer Merck & Co, which pulled Vioxx from the market in October 2004 after regulatory agencies learned that it doubled the risk of heart attack and stroke.

The *NEJM* had asked for a correction to the randomized study, which concluded that Vioxx caused fewer gastrointestinal problems than the older anti-inflammatory naproxen. But Bombardier's academic group refused, countering in a response that the researchers followed "appropriate clinical trials principles." The heart attacks in question, they said, occurred after a pre-specified termination date for reporting cardiovascular toxicities (which was a month earlier than the cut-off date established by Merck for reporting gastrointestinal problems). Including the additional heart attacks would not have appreciably affected risk calculations, the researchers argued.

NEJM editors were unconvinced, noting that an internal Merck memorandum indicated 4 months before publication that there were 47 thromboembolic events in the Vioxx arm of the trial and 20 in the naproxen arm. Merck's selection of the cut-off date for cardiovascular events was an "untenable feature of trial design," the journal editorial said.

It was not the norm, at that time, for cut-off dates to be reported in journals, Bombardier told *CMAJ*. The study was focused on gastrointestinal safety, she says. Just weeks before the study closed, the arm's-length data safety monitoring committee saw a trend in cardiovascular events but "decided not to notify the steering committee because they were not making a recommendation to stop the study and they didn't want to unblind the steering committee, because the study was still ongoing. It was still in the process of closing out," she says.

"Merck wanted to comply with the recommendations of the data safety monitoring committee and they made a decision, in advance, to have an earlier cut-off point, so that they could adjudicate and still meet the deadlines that we had set," Bombardier added.

The academic participants in the study conducted a review of all aspects of the trial "and we were satisfied that this decision [to fix an earlier cardiovascular cut-off date] was made by Merck before the events occurred," Bombardier said.

The Toronto researcher called the events "a very unusual set of circumstances. And does it change the results? No."

Karen Pedersen, media relations manager for the *NEJM*, says this is only the third time that the journal has attached an expression of concern to a study. It is the first time that authors refused to issue a retraction or correction in response.

The editors felt that they should have been informed of the different termination dates for cardiovascular and gastrointestinal events, Pedersen said.

The expression of concern and the authors' response are both permanently attached to the study and will appear every time anyone accesses the original study in the future, Pedersen said. — Wayne Kondro, Ottawa

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