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 throm-

boembolic 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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