low-risk patients enter a US-style chest pain program, including stress testing before discharge.

Brian Steinhart has concerns about the proportion of missed patients who had anti-ischemic treatment or follow-up diagnostic testing (or both). Our definition of missed patients included only patients who were discharged without any anti-ischemic treatment and without specific follow-up evaluations or testing booked. In only 1 of the 21 cases did the patient end up, many days later, in a cardiology clinic, but we could not confirm any predischarge planning for this appointment. The definition of clinically significant adverse outcomes is an interesting one. The single patient who died had significant comorbidity, and the death was not unexpected. However, 10 of the 21 "missed" patients had a 30-day diagnosis of acute myocardial infarction (AMI). One had an elevated troponin level known by the treating physician but discounted as a false positive. The others re-presented with evidence of myocardial necrosis, and it is likely that the index presentation was unstable angina that could have been treated more appropriately (and the AMI potentially averted). There appears to be no consensus on whether this should be considered inappropriate management; however, our position is that the diagnosis of acute coronary syndrome should be made with the greatest possible accuracy on initial presentation and that each missed case is inappropriate.

We agree that there were differences in methods between our study and that of Pope and colleagues.[3] We did not include some critically ill patients, but these patients by definition would not be missed. They may have had a small impact by increasing the denominator modestly. Steinhart contends that if we had used the methods outlined by Pope and colleagues, our rate of missed cases would have been lower than 5.3%. Although this is probably true, the question is which method is more appropriate. We prespecified detailed definitions for AMI and definite unstable angina and followed up patients very carefully and therefore are confident in underscoring our rate of missed acute coronary syndrome.

We encourage others to measure outcomes in patients with chest pain and challenge all to develop consensus on a more appropriate definition of clinically significant missed acute coronary syndrome.

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Rethinking diabetes care in Canada

In a study published last year in *Canadian Family Physician*, Harris and associates[1] found evidence that many Canadians with diabetes are not being monitored appropriately: 16% had not had their glycosylated hemoglobin (A1C) level tested in the preceding year, 85% had not been assessed for diabetes-related foot conditions, and more than half had not had their lipids tested. Clearly we are doing something wrong.

The Canadian Diabetes Association (CDA) published state-of-the-art clinical practice guidelines[2] in the same year as the Harris study appeared. These guidelines are a tremendous resource, but I am concerned that they will not improve the delivery of diabetes health care unless we abandon the traditional top-down approach and replace it with a bottom-up strategy.

What would such a bottom-up strategy entail? We should ensure that diabetic patients become intimately familiar not only with the traditional tenets of diabetes education (e.g., proper nutrition and exercise therapy, blood glucose testing) but also with traditionally physician-centric issues such as target levels for A1C, lipids, microalbumin and certain clinical parameters including blood pressure and 10-g monofilament testing. There is no reason that patients cannot be knowledgeable enough to ask their physicians if they should be taking acetylsalicylic acid or an angiotensin-converting enzyme inhibitor or a statin or to ask about — and be engaged in discussions regarding — the implications of abnormal clinical parameters (such as impaired 10-g monofilament sensory awareness).

That the guidelines are available online[3] is helpful, but because they are written for a professional audience, many people with diabetes are unlikely to use them. So how about an online lay version of the guidelines? Why not encourage pharmacists to distribute CDA-designed information sheets instead of noncontextual (and at times alarmist) lists of potential adverse drug effects? Why not duplicate the American-based Lower Extremity Amputation Prevention (LEAP) program,[4] which distributes free monofilaments for patient (and professional) use? Or even enclose a monofilament and instruction sheet with every new prescription for an oral hypoglycemic agent?

I believe that Canada could be at the forefront of a change to bottom-up diabetes management in the same way that we have been (and continue to be) at the forefront of diabetes research. And I believe that such a change will create a better informed, more engaged and, ultimately, healthier diabetes patient population.

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Final evaluation results for the Fast-Check HIV rapid test kits

In late April 2002, the British Columbia Centre for Disease Control (BCCDC) reported to Health Canada potential problems with the Fast-Check HIV-1/2 point-of-care whole blood (POC WB) test (BioChem ImmunoSystems). On the basis of these data, Health Canada issued a safety advisory,[1] and the test was withdrawn on Apr. 29, 2002.[2] Beginning in the same month, but before the product was withdrawn, the BCCDC began a prospective evaluation of the test in 100 HIV-positive patients undergoing routine care at St. Paul's Hospital in Vancouver, to obtain more systematic data on sensitivity. The study was approved by the Institutional Review Board of the University of British Columbia. In July 2002, we reported results from the first 63 specimens in a letter to *CMAJ*,[3] and this follow-up letter summarizes the results for the entire sample of 100 patients. These data are important because at least one new POC rapid HIV test is now undergoing clinical trials in Canada.[4]

Overall, there were 75 reactive test results (true positives), 12 nonreactive test results (false negatives) and 13 inconclusive results. The sensitivity of the test was 88% (88/100) if inconclusive results are classified as tentatively reactive, 75% (75/100) if inconclusive results are classified as nonreactive and 86% (75/87) if inconclusive results are excluded (Table 1). We believe that, in a clinical situation, inconclusive results would have been classified as tentatively reactive to minimize the number of false negatives and since all positive test results would have been confirmed by another test.

Table 1 shows the test sensitivity for subjects receiving and not receiving treatment, for those with detectable and undetectable viral loads and by CD4 count. There was a trend to higher sensitivity with lower CD4 counts, but this was not statistically significant ($p = 0.37$).

Because this study did not include specimens from HIV-negative subjects, we cannot comment on the specificity of the test; however, classifying inconclusive results as tentatively reactive would likely reduce the specificity.

In summary, the sensitivity of the POC WB test was unacceptable even for untreated patients with detectable viral loads, and the product recall in late April 2002 was the correct move. These results emphasize the necessity of a robust quality assurance program before any new POC rapid HIV test is licensed.

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A question of ethics

A recent *CMAJ* editorial about the outbreak of *Clostridium difficile*-associated diarrhea in certain Canadian hospitals[1] describes the "stifling of concerned voices on the front lines of medicine" as the "worst news" in a bad-

Table 1: Sensitivity of Fast-Check point-of-care whole blood rapid HIV test

Category for inconclusive results	Disease characteristic*; sensitivity of test, %										
		Patient undergoing treatment			Detectable viral load			CD4 count†			
	Overall	Yes	No	*p*	Yes	No	*p*	< 200	200–500	> 500	*p*
Reactive	88 (88/100)	86 (69/80)	93 (14/15)	0.68	89 (48/54)	79 (22/28)	0.32	84 (16/19)	89 (42/47)	76 (13/17)	0.37
Nonreactive	75 (75/100)	72 (58/80)	80 (12/15)	0.75	72 (39/54)	68 (19/28)	0.46	79 (15/19)	74 (35/47)	53 (9/17)	0.20
Excluded	86 (75/87)	84 (58/69)	92 (12/13)	0.68	87 (39/45)	75 (18/24)	0.32	83 (15/18)	88 (35/40)	69 (9/13)	0.29

*The total number of subjects within each disease characteristic is less than 100 because data were missing for some patients for some characteristics.
†Fisher's 2-sided exact test.