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Competing interests: Dr. Blumer is a coauthor of *Diabetes for Canadians for Dummies* (Wiley & Sons, 2004).

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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 On the basis of these data, Health Canada issued a safety advisory,[1] and the test was withdrawn on Apr. 29, 2002.[2] Beginning in the same month, but before the product was withdrawn, the BCCDC began a prospective evaluation of the test in 100 HIV-positive patients undergoing routine care at St. Paul's Hospital in Vancouver, to obtain more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, %										
	Overall	Patient undergoing treatment			Detectable viral load			CD4 count†			
		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.

news story.

What causes silence in such situations? Health care "insiders" are frightened they might make the situation worse. They worry that disclosure of problems will be seen as unjustified criticism, not just of the current state of affairs in the health care system, but also of health care professionals — in some cases colleagues — who are already stretched to their limits, demoralized and working miracles in very difficult situations. There is a risk of being labelled as not being team players, as troublemakers, as self-serving in some way, or as "the enemy" — whistleblowers often are — and of suffering the consequences of such stigmatization. Those consequences can include loss of professional opportunities, promotion, prestige, a congenial work situation and even friendships.

Addressing these problems is complex, and it would be a grave mistake to think otherwise. But I would like to make a few suggestions as to where we might start. First, we must recognize that it can be seriously unethical to not speak out and to not change a culture that does not recognize the necessity of open disclosure. Furthermore, it is not only people who can be unethical; systems can also be unethical. Therefore, we must try to design ethical hospital systems. At the least that requires protecting those who try to prevent or correct breaches of ethics — for instance, whistleblowers — and ensuring that the organizational structure does not create or condone what Nuala Kenny calls "ethical distress."[2] A person experiences ethical distress when he or she knows that another is acting unethically but, because of lines of authority, is powerless to do anything about it or would suffer serious repercussions by doing so. In short, we need a comprehensive system of identified corrective mechanisms and remedies for such situations.

Finally, many ethical mistakes are made because an ethical problem is not recognized as such, but rather is wrongly identified as a public relations or communications problem. Instead of asking what ethics requires in the situation, those involved ask, "Will it make the minister, the hospital, etc., look bad, and if so, how can we avoid that?" The problem is spin-doctored, a process that often augments the ethical wrongs, as for example in deciding for public relations reasons not to tell the public about risks or tell patients about mistakes.

I once heard a PR person give the following advice: "Never say you don't know. Never say you were wrong. And never apologize." How not to do ethics, in a nutshell.

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The doubts and fears of emergency physicians

My colleague Dr. Ursus describes the emotional turmoil of working in an emergency department.[1] As an emergency physician myself, I have faced some of the same questions and concerns, but I have also gained a few pearls of wisdom from my patients, their families and the emergency health care team.

First, nobody expects the physician to be infallible, although patients do expect honesty, caring and loyalty. Over the years, many have forgiven my mistakes, as long as my efforts to help were perceived as genuine. Families have found solace in the fact that I could show my emotions, but virtually none of my patients were offended when I could not tell them exactly what was wrong with them. They were quite ready to accept that I could only reassure them about what was *not* wrong and provide some relief for their suffering.

Similarly, members of the emergency health care team can accept the fact that, at times, our hands tremble and we have doubts. In fact, these caregivers are themselves plagued by fears and worries. The essence of emergency medicine is dealing with the unknown and working with frightened patients. We have to make rapid yet appropriate decisions, often with virtually no information or proper resources. The burden is enormous, and one person cannot do everything alone; the load must be shared.

Being an emergency physician is far from being "small," and the only expectation one need live up to is one's own. Similarly, the only guarantee we must give is that we will endeavour always to be the patient's advocate and to provide our best effort.

I ask Dr. Ursus not to succumb to fear, not to fake omniscience and never to hide his or her humanity. The best emergency physicians I know are the ones who care about their patients and are emotionally honest with themselves.

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Clostridium difficile colitis: A marker for ischemic colitis?

In an electronic letter published in *Gut* earlier this year,[1] I wrote, "Nine years ago I alerted the CDC [US Centers for Disease Control and Prevention] in Atlanta to the possibility that *C difficile* colitis might be a marker of a far more common and potentially serious disorder [than *C. difficile* colitis], ischaemic colitis."[1] The same possibility should be considered in the current