Patients suffer when labs get it wrong

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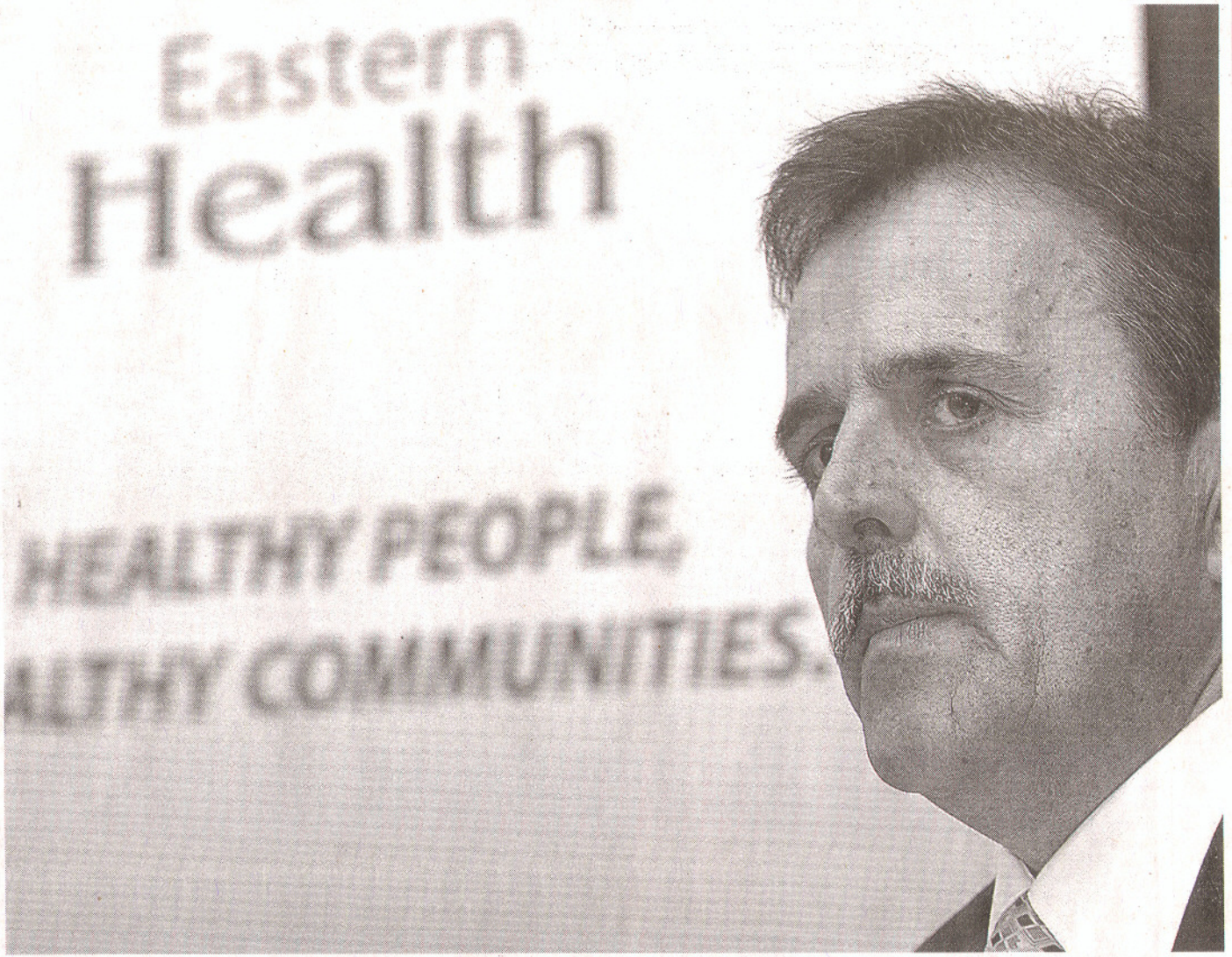
About 85 per cent of decisions that physicians make about diagnosis and treatment of patients are based on laboratory tests, from blood tests through to cancer biopsies.

Bodily fluids (or solids) are collected and, magically, the results come back.

Except there is no magic involved – just lab workers toiling away to provide quick and accurate results, and pathologists and others interpreting those results.

Despite its ubiquity and importance, we rarely give a second thought to testing. That is a huge mistake – for both individuals and the health system as a whole – one that has been driven home painfully by the horrific story involving some breast-cancer patients in the Eastern Health Region of Newfoundland.

The details are still sketchy but we know this: In the summer of 2005, an oncologist who doubted the validity of a test asked that it be redone.



George Tilley, CEO of Eastern Health, apologizes for the lack of information given to cancer patients regarding lab results. RHONDA HAYWARD/CP

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The patient, initially deemed to have hormone receptor negative breast cancer, was found to be positive.

(The test measures the amount of certain proteins, called hormone receptors, in cancer tissue. A high level means that the cancer may respond well to a hormonal treatment such as Tamoxifen.)

Because of the concerns, 969 samples of breast-cancer tumours collected between 1997 and 2005 and deemed hormone receptor negative were sent to the lab at Mount Sinai Hospital in Toronto to be retested.

Of that total, 763 women were still alive.

Retesting revealed that 317 of them had received inaccurate results. (The accuracy of the tests in the 206 women who had died is unclear.)

Of the 317 patients with inaccurate test results, 104 had their treatment changed, including 96 who were prescribed Tamoxifen.

From this flurry of numbers, only one thing is important to retain: The error rate for estrogen-receptor tests was almost 42 per cent for eight long years.

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That is truly shocking. It suggests an utter lack of quality control at the lab.

In every aspect of our health system there must be standards, and there must be checks and balances. Nowhere is that more true than in the lab.

It would be easy to point a finger of blame at the lab technicians.

But in the mid- to late 1990s, there were severe funding cuts in health care, and invisible sectors like laboratories and pathology were savaged.

The government of Newfoundland and Labrador has announced that there will be a judicial inquiry into the testing debacle.

The presiding judge needs a broad mandate to examine the all-too-unknown world of laboratory testing, from how it operates through to how the quality is monitored.

The judge must also have the power to demand answers from the administrators and politicians who are ultimately responsible for the health system, and its labs.

Eastern Health officials suspected in early 2004 (when they purchased new equipment) and knew definitely in 2005 that there were serious problems with hormone-receptor tests.

Yet breast-cancer patients and the public were told nothing.

When bare-bones information was released publicly in December, 2006, it was only after legal proceedings began.

And even last week, after the news media caught wind of the story, elected and non-elected officials continued their mealy-mouthed ways.

The CEO of Eastern Health, George Tilley, apologized for the "confusion" that resulted from the failure to disclose, and Minister of Health Ross Wiseman sidestepped questions on the grounds that there were ongoing legal proceedings.

The only confusion here is to be found in the priorities of officials who have put butt-covering ahead of patient safety.

The final report of the commission of inquiry on the blood system in Canada, headed by Mr. Justice Horace Krever, contains a lifetime's worth of wisdom.

That report shows that, in a complex health system, mistakes can happen.

When procedures break down, harm can occur and people can die.

But the most egregious, lasting harm comes from trying to play down, hide and deny mistakes and failures.

Breast-cancer patients in Newfoundland were harmed by faulty test results.

They are owed an unabashed apology, and perhaps compensation. (As Judge Krever recommended, there should be no-fault insurance to deal with these tragedies, not lawsuits.)

Health officials need to get it through their heads that they must tell the truth, the whole truth and nothing but the truth.

Until they do, none of us should feel perfectly safe in the health system.