

Cancer Labs no closer to national standards

Despite fresh doubts about tests in B.C. and damning report on Newfoundland scandal, efforts to set quality benchmarks are stalled

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As news emerges this week of potential breast cancer testing mistakes in B.C., efforts to create national quality assurance standards to prevent lab errors and misdiagnosis have stalled - even though a damning report on Newfoundland's testing scandal warned of the consequences of failing to modernize the system.

Dozens of breast cancer lab tests in British Columbia, done between May of 2005 and October of 2006, are being reviewed after the former clinical director of the Okanagan Health Service Area Laboratories, pathologist Kirk Ready, voiced concerns that a lack of uniform practices for conducting tests may have put them at risk of misinterpretation.

In an interview yesterday, Dr. Ready described "many deficiencies" in the Okanagan labs, governed by the Interior Health Authority.

"It's scary," Dr. Ready said. "If I hadn't brought this forward, would they have actually done a review?"

B.C. Health Minister George Abbott has said the province is taking Dr. Ready's allegations very seriously, and that Interior Health is conducting a review to determine if any tests were misinterpreted. The review should be complete in about two weeks, according to Interior Health.

The safety issues highlighted by Dr. Ready, such as the absence of standardized procedures for reporting results and which tissue fixatives should be used to prepare test slides, aren't isolated to B.C. Leading Canadian pathologists say they're a symptom of a much wider problem that is putting patients across the country at risk.

"Patients' health can't just be allowed to suffer because the appropriate mechanisms aren't in place," said Jagdish Butany, president of the Canadian Association of Pathologists.

The problem has led to a deadly prediction from one of Canada's most respected pathologists: More patients will fall victim to testing errors that could lead to improper treatment or death unless urgent action is taken to fix an ailing system.

"We have practical evidence of what happens when one test is of poor quality in terms of the personal cost, in terms of the costs of inappropriate therapies and complications," said Blake Gilks, pathologist at Vancouver General Hospital and acting head of the pathology department at the University of British Columbia.

The evidence Dr. Gilks refers to is the breast cancer testing scandal that has unfolded in Newfoundland, in which nearly 400 breast cancer patients received inaccurate results from critical tests.

But several other reports of pathologist error have surfaced in the last year, casting doubt on the ability of labs to adequately police themselves:

A review of Winnipeg pathologist Robert Stark's work found errors in 42 cases, including two in which patients received the wrong cancer diagnosis;

An investigation was launched into work by Owen Sound, Ont., pathologist Barry Sawka after a review found a six-per-cent error rate and missed cancer diagnoses in his work;

A public inquiry was held in New Brunswick after an audit found work by Miramichi pathologist Rajgopal Menon to be inaccurate and incomplete.

The Newfoundland cancer testing scandal also led to a public inquiry and urgent recommendations to improve quality assurance measures. Madam Justice Margaret Cameron, who released her recommendations in March, said the best way to prevent a public health disaster is the creation of a government-backed national program for accreditation and quality testing at hospital labs.

It's exactly what the Canadian Association of Pathologists and many in the laboratory community have been calling for since news of the breast cancer testing scandal surfaced.

The forefront of the system the association advocates would be uniform standards for the preparation and execution of medical tests, such as immunohistochemistry tests, which must be painstakingly prepared and are difficult to interpret.

To change the system, pathologists say they need the authority and financial power of governments, particularly at the federal level.

Newfoundland's Health Minister Ross Wiseman said provincial efforts can only go so far, and that federal involvement could help ensure its success.

"If we're committed as [provincial] health ministers, I think it will become incumbent upon the federal government," Mr. Wiseman said. "I think it's a very important piece to make this a success."

Federal Health Minister Leona Aglukkaq declined to be interviewed for this story, but her press secretary said in an e-mail the federal government will not become involved because "the regulation of pathologists and laboratories is a provincial and territorial responsibility."

UNEVEN QUALITY

Quality assurance of pathology services is a patchwork system across Canada, with some provinces lacking basic accreditation regimes for labs.

Ontario and B.C. are often held up as examples, with dedicated laboratory accreditation bodies and sophisticated proficiency testing, while Eastern provinces are viewed by many pathologists as lagging, due partly to lack of funds and remote location of labs.

But even the quality of B.C. and Ontario labs has faced questions after reports of potential testing issues, including the problems outlined by pathologist Kirk Ready, former clinical director of the Okanagan Health Service Area laboratories.

The Canadian Association of Pathologists announced plans last year to create a cross-country quality assurance program that would replace the patchwork system.

Association president Jagdish Butany said they've had some success, such as plans to launch a new pathology medical journal this year.

One of the biggest advances in pathology quality control has been a proficiency program that tests how well labs interpret results for three complex breast cancer tests, including tests at the centre of the Newfoundland inquiry. But the program's future is in question since it's voluntary and has little funding.

Without political investment, advocates for change fear pathology programs will remain as they are today: Critically under-staffed, under-funded and lacking quality assurance programs to catch potential errors involving cancer and other medical tests.