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Subject: Flawed test imperils Nfld. cancer patients - Globe and Mail

Flawed test imperils Nfld. cancer patients
By PETER GULLAGE

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ST. JOHN'S — Newfoundland and Labrador breast cancer patients are in a **frightening limbo** as **hundreds** of tissue samples dating back to 1997 are being retested after **major flaws** in a laboratory test were uncovered.

The problem was discovered in May when a test for hormone receptors in the cancer cells of a patient who had fallen ill in spite of testing negative, gave a different result than earlier tests. The hormone receptor test determines if cells are stimulated by either estrogen or progesterone and indicates cancer-cell growth. The original test was negative, but in May, the patient's tissue tested positive, and as a result the province's breast cancer testing program was suspended.

"With 40 steps in the [testing] procedure, if you have a problem in any particular step, it can affect the results you get," explained Bob Williams, vice-president of quality diagnostic and medical services for the Eastern Health authority. "There are checks and balances in there, but in this case, in some of these cases, these things did not appear to work."

In July, the authority called on Toronto's Mount Sinai Hospital to test previously screened tissue and to take on the lab work for all new breast cancer patients. Health-care officials say they can't be precise about the number of people affected. Mount Sinai is testing 30 per cent of the hundreds of tissue samples that came up negative since 1997. So far, 10 per cent of results have changed to positive.

A different result "may have implications for patient care and that's the issue that's discussed with the patient's treating physician and then treatment may be modified based on that," Dr. Williams said.

The troubles in the lab are a worry for breast cancer survivors who have to wait for news about the new tests on their tissue.

"My breast cancer pathology came back as estrogen negative but partially progesterone positive, so it is possible that there was an error in my pathology," said **Gerry Rogers, a breast cancer survivor who turned her ordeal into an award-winning documentary.**

"It's hard to know that maybe a mistake has been made."

Patients who test positive for hormone receptors may be offered Tamoxifen, a drug that interferes with estrogen and progesterone over a five-year treatment. Ms. Rogers wonders where her breast cancer tissue sample is in the process and whether it's too late to take the drug.

"If the case were to be that in fact there was an error in the pathology, then the window of opportunity for the effectiveness of Tamoxifen in my case has kind of passed," she said.

Peter Dawe, director of the Newfoundland and Labrador chapter of the Canadian Cancer Society, warns that this "has the potential to be a big issue" for the province's health-care system and patients.

"It alters the treatment. You could be having an inadequate treatment based on a test result," Mr. Dawe said.

"There is a group that has the test result in question and our fear is that they should have received treatment and didn't."

CC: Chaplin, Carolyn; Cheeseman, Josephine