

From: Tansy Mundon
To: Abbott, John; Furlong, Tara; Hennessey, Moira; Hunt, Ed; Hynes, Darrell; Ottenheimer, John
Date: 10/5/2005 4:41:14 PM
Subject: CBC online story - Newfoundland cancer lab produces false results

FYI, this story was based on today's Telegram story. I was speaking to Susan B. this afternoon and she advised that CBC did not do an interview for this story. To date, Eastern Health received six calls today and five calls yesterday. The nature of the calls were primarily around confusion around mammography testing as opposed to ER/PR.

Peter Gullage did call Eastern this afternoon and requested an interview on the issue for a story he's doing for The Globe & Mail. His focus seems to be on the impact on patients. Dr. Williams did an interview with him this afternoon but Susan had not talked to him as of 10 minutes ago.

Essentially you can look for two stories in tomorrow's Globe - this one and another on the ATIPP request for MCP billings.

Tansy

Newfoundland cancer lab produces false results

Last Updated Wed, 05 Oct 2005 10:45:44 EDT

CBC News

A major cancer-testing laboratory in Newfoundland has produced unreliable results.

The lab is located at the General Hospital in the Health Sciences Centre in St. John's. It does the majority of cancer tests annually in Newfoundland and Labrador.

The Eastern Health Authority said Wednesday all samples are now being sent to Mount Sinai Hospital in Toronto.

According to the St. John's Telegram, the concern started in May when an initial test on a patient indicated that tumour cells were not cancerous. But after receiving new information on the patient's condition, the same sample was retested and showed a positive result.

Dr. Bob Williams, a vice-president of the health authority, says that as an added precaution results received as far back as 1997 also are being sent to Mount Sinai for retesting.

Williams said that 73 per cent of the tests performed in the past were positive, but the lab is mostly concerned with the 27 per cent of tests that were negative.

He said about 10 per cent of the tests performed over the past seven years may show conflicting results. The discrepancies were in tests for breast cancer. The authority receives seven or eight such samples each week.

The reason for the conflicting results is not known, but last year the facility brought in a new fully automated system for detecting hormone receptors in breast tissue. An older system required more steps in the testing process.

Williams said Eastern Health contacted other labs across the country, reviewed some literature and consulted oncologists and surgeons.

"After consultation it was determined that we should, in the interest of patient care, retest all patients who had tested negative".

Lab results from Mount Sinai are expected in about a month.

A quality review of the St. John's lab also is underway.

CC: Chaplin, Carolyn; Cheeseman, Josephine

From: Tansy Mundon
To: Abbott, John; Hunt, Ed; Hynes, Darrell; Ottenheimer, John;
susan.bonnell@easternhealth.ca
Date: 10/6/2005 9:14:18 AM
Subject: Flawed test imperils Nfld. cancer patients - Globe and Mail

Flawed test imperils Nfld. cancer patients
By PETER GULLAGE

Thursday, October 6, 2005
Posted at 7:41 AM EDT

Special to The Globe and Mail

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

18

From: Tansy Mundon
To: Abbott, John; Hennessey, Moira; Hunt, Ed; Hynes, Darrell; Ottenheimer, John; Vivian-Book, Lynn
Date: 10/12/2005 3:07:16 PM
Subject: Media requests

In case we didn't realize that CBC was back - they are. And the number of media requests reflects it.

Here are the requests received and the responses:

CBC Radio Morning Show - requesting Faith do an interview (live) on the morning show tomorrow at 7:10 am regarding the annual flu vaccine. (ARRANGED)

CBC Radio (Nancy Walsh) - requested an interview regarding the Wheadon case. (Declined)
Inappropriate to comment while the case is before the court).

NTV (Colleen Lewis) - Doing a follow up story with Central Health regarding extension of tender by two weeks. Is the project still on schedule. (It is my understanding that this interview is taking place today. I also called Colleen earlier today to reiterate that the project is on schedule)

Eastern Health inquiries

CBC Radio (Mark Quinn) - ER/PR (it hasn't gone away). Mark is doing a debrief of the issue and has caught on to the fact that this may be an issue nationally. Dr. Williams spoke to him earlier today and I expect this story to air tomorrow morning.

CBC Radio (Cecil Haire) - Doing a piece on wait list management. Deborah indicated that one of their VPs is doing an interview with Cecil tomorrow morning. I referred Deborah to our September 22nd news release to ensure our messages are consistent.

CC: Furlong, Tara

John Ottenheimer - Unreliable tests gives lesson to all labs

From: Tansy Mundon
To: Abbott, John; Furlong, Tara; Hennessey, Moira; Hynes, Darrell; Ottenheimer, John
Date: 10/20/2005 8:08:46 AM
Subject: Unreliable tests gives lesson to all labs

Unreliable tests gives lesson to all labs

Last updated Oct 20 2005 07:20 AM NDT

CBC News

Tissue samples from some breast cancer survivors in Newfoundland and Labrador are being retested after a lab problem that could be repeated across the country, a medical technology expert warns.

The hormone receptor test shows if cancer cells respond to hormones. If the results are positive, patients are usually treated with the hormone therapy tamoxifen.

Zita White

Reliability problems with the test in St. John's were discovered when a patient fell ill despite a negative test result, and the tissue later tested positive.

FROM OCT. 14, 2005: Flawed cancer tests raise patients' concerns

Zita White of Happy Valley-Goose Bay, Labrador, and hundreds of other women are waiting to find out if they received the correct treatment. People with a positive test result are usually treated with tamoxifen.

"If I had tested positive, I would have been given the drug tamoxifen, which would have greatly lowered my chance for recurrence," said White, who as far as she knows, is cancer-free.

Officials at the St. John's lab acknowledged the problem, but they don't yet know what went wrong.

"There's 40 steps in that process," said Bob Williams, a vice-president at the Eastern Health regional authority. "Any problem in any one step can cause a problem with the testing results."

Problems with the test are not new. The medical literature shows test results have varied widely between labs in Europe. Williams said its prompted the lab to take another look at their testing procedure at the health authority.

Dr. Brian Hewlitt

Canada lacks a national standard body for the tests, said Dr. Brian Hewlitt, an expert in medical technology. He said labs across the country should take a look at what they're doing to make sure they are getting it right.

"I think the laboratories performing the testing are duty-bound to do some peer comparison, to take their material and have it tested in another centre and compare the results," said Hewlitt.

"On the basis of that, then you may or may not wish to become severely worried."

Breast cancer patients in Newfoundland are scrambling for answers.

"There is absolutely no doubt that there is a group of women out there that didn't get proper treatment, and that could have very dire consequences," said Peter Dawe, director of the Newfoundland and Labrador chapter of the Canadian Cancer Society.