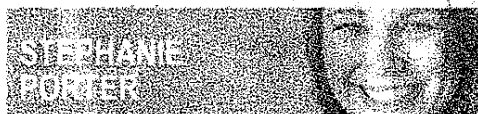


'Out there'

Eastern Health breaks silence on inaccurate breast cancer results



Eastern Health broke a yearlong silence this week, addressing the media about the results of their decision to re-test nearly 1,000 breast cancer specimens to address possible inaccuracies.

Eastern Health says 117 breast cancer patients were "identified as requiring treatment changes," as a result of the new tests and subsequent case reviews. There is no one issue or

mistake that led to the changes, according to the organization; rather, it was "a systems problem."

The exact number of incorrect results was not released, due in part to a pending class-action suit against the health authority. Meantime, the number of registrants in the class action is growing steadily, with lawyer Ches Crosbie reporting at least three new participants in the past week — raising the total to more than 40.

When *The Independent* broke the story of the inaccurate tests in October 2005, there was a flurry of media appearances by hospital officials. Since then, spokespeople have repeatedly

turned down requests for interviews, deferring any public statements until all test results were in and all patients contacted.

"We were criticized for not being out there in the public," cancer program clinical chief Kara Laing tells *The Independent*. "But we felt that we had to take the time and the energy we had and we had to focus it on the patients and that we couldn't really spend a lot of time out in the broad public arena.

"Until we had the opportunity to meet with and decide what we were going to do with

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'I hope I never have to do it again'

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every single one of the patients — although we knew there was the whole element of the public trust — at the time, our main focus was on the patients."

At issue are the outcomes of seven years' worth of estrogen and progesterone receptor (ER/PR) testing, done at the laboratory at the Health Sciences Centre in St. John's.

The tests, conducted on tissue samples from breast cancer tumours, are used to guide oncologists in determining the best therapy for the patient after surgery.

A positive test result means the patient may respond to hormone therapies, such as the drug Tamoxifen — which is taken by mouth and generally thought to carry less side effects than chemotherapy. A negative test result means hormone therapy is not an option.

The ER-PR test is not an exact or simple procedure. In 2004, a new semi-automated system, called Ventana, was installed in the Health Sciences Centre laboratory. It replaced the Dako System, a more complicated, manual procedure, involving more than 40 steps.

Nash Denic, chief pathologist of the laboratory program, gave media representatives a tour of the labs last week. From room to room, machine to machine — from watching tiny samples being taken from a kidney tumour to looking through a microscope at treated tissue — he explained the procedure.

"I want to show you the complexity of doing the test," he says. "I hope I don't leave you more confused than before."

Eight million tests are completed in the lab every year, says Denic, of which between 300 and 400 are ER/PR.

Even with the new, more automated system, there are a number of steps, and the end result is a matter of judgment — different doctors may look at the final sample and offer slightly different results.

What constitutes a positive result is also changing. At one time, if fewer than 30 per cent of cells were positive, it would be considered a negative result. That benchmark has fallen in recent years, to 10 per cent, and even down to one per cent — today, an oncologist may decide to use hormone therapy to treat a cancer with any sign of positivity.

"Ten years from now, we might be saying 90 per cent of tumours are positive, where now we say it's 75," says Laing. "The testing may get better, the antibodies may get better. What we know about things is changing all the

time."

With all the media coverage this week, lawyer Ches Crosbie — who has filed the application to be certified as a class-action — has received three more registrations from women wanting to be part of the class action suit. That puts the total "in the 40s," he estimates.

"I guess this reminded them of the whole situation," he says. "Well, they're members (of the lawsuit) anyway, in the sense that they're in unless they opt out when notice is given after certification," he says. "But people have been indicating an interest in being in the class."

The suit is being filed on behalf of women (and men) who fall into three categories. First, a large class of people whose retests did not result in any changes — but the process caused the women unnecessary stress and anxiety. That class could be 1,000 or more.

Secondly, he represents those whose initial test were shown to be incorrect, or who may have been offered a treatment that was not ideal, which may have affected the outcome of their cancer.

Third — and this may not be strictly related to the results of the ER/PR tests — Crosbie represents a small group of women who may have had unnecessary surgery.

Myrtle Lewis, who was profiled in *The Independent* last July, had both breasts and a number of lymph nodes removed seven years ago, and underwent months of debilitating chemotherapy. Last summer, she says, her doctor revealed that the review of her file indicated her cancer may not have been as invasive as originally believed — indeed, she may never have needed the double mastectomy. She's not the only one.

"I was contacted by a lawyer for a woman in the same position this week, so that makes three, I guess, who I've been told about," says Crosbie.

"Three people whose pathology was misread as being cancer and who received a mastectomy — but it wasn't cancer in that sense, it was cancer in situ (similar to precancerous cells)."

The problem is wider than the reading of the ER/PR tests, he says.

"It's a problem with pathology and quality control in pathology. And we're arguing that there effectively wasn't any."

Eastern Health is not commenting on the lawsuit.

Laing was part of the eight-person "tumour board" (two oncologists, two surgeons, two pathologists, a representative from the quality department and one support person) tasked with reviewing

the complete file of every patient whose specimen was sent to Toronto for retesting — many of whom may now be involved in the lawsuit.

The board met every Thursday night for months, slowly working through the paperwork, charts, and files.

"It was a stressful time because we were worried about our patients," says Laing. "I don't think I would have changed how things happened or unfolded, but it was a lot of extra work."

"It wasn't something that you could just say, 'everybody do this for two months or six months until it's all sorted out,' because this needed to be done in addition to the regular day-to-day work and new patients. I hope I never have to do it again."

Oscar Howell, the new vice-president of medical services for Eastern Health, says the past year has been "pretty stressful for (medical staff), as it was for cancer patients." He keeps his tone optimistic though, touting advances in cancer diagnosis and treatment, and the strength of the doctors — if not the quantity.

"We do have a shortage of pathologists now, and that concerns me greatly, and we are trying to recruit additional pathologists," he says.

"If there's good that came out of it, it's that this will allow us to make this part of the lab the best it can be ... and if we can take the learning from this and extrapolate that back through our entire laboratory, I would hope that we would make it so good we will attract a lot more people."

Looking back on the media presentations and interviews she participated in this week, Laing says she found the process "difficult," adding that she found the tone "demanding, accusatory, like there's some big thing we're hiding from everybody."

Laing maintains there is no big secret being protected from the public's always critical — and often cynical — eyes.

"(We've) made the lab better," she says. "We have a core group of people doing things in the lab; you now have stability in the oncology workforce. You now have people who are paying attention, not just to this, but to all things that are happening — so if things start to appear out of sync, you can look at it now."

"It really was a systems problem and we've done everything we can to fix the problem and we hope other labs learn from this."

The lab at the Health Sciences Centre will start conducting ER/PR tests again in an estimated two months.

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From the beginning: the chronology

May 2005: The first evidence surfaces that an estrogen/progesterone receptor (ER/PR) test had given a false negative, according to Eastern Health. An oncologist was treating a breast cancer patient, and "given the nature of this woman's cancer, her age and other factors, the oncologist requested the test be repeated," states Eastern Health. The new test, using updated technology, converted to a positive result.

Five more negative patients are retested — all also converted.

June 2005: Medical staff decide to retest all negative results from 2002 to determine if the cases were isolated. All labs in the province are asked to send specimens to St. John's for retesting.

Over the next two months decisions are made to retest all ER/PR negative patients as far back as 1997, and that an external laboratory — Mt. Sinai Hospital in Toronto — should conduct the tests, according to Eastern Health. Almost 1,000 specimens would be sent off.

Early October 2005: The first set of results arrive from Mt. Sinai, according to Eastern Health. As results become available, patients are contacted, one by one.

October 2, 2005: *The Independent* learns about the retesting, and brings the story to the public's attention for the first time. Other local and national media follow.

Dr. Kara Laing, cancer program clinical chief with Eastern Health, speaks with *The Independent*. "The reason we haven't gone public with this is we don't have all the answers," she said. "The last thing you want to do or we want to do is make people afraid ... is to cause some sort of mass hysteria."

Eastern Health purchase advertising to inform the public of the retesting. Patient relations officers begin calling all patients who had been retested.

(In an interview this week, Laing says there were "hundreds of patients contacts and encounters," and many times that number in incoming phone calls. "There was a lot of anxiety, a lot of phone calls, a lot of meetings to be arranged — not just breast cancer patients who had a change, but all the breast cancer patients ... then there were other cancer patients calling in, 'should I be concerned? Does this affect me?'")

October 2005: According to Eastern Health, a tumour board is set up to review the complete medical file of every patient that had been retested, as

the results arrive.

The external review process of the laboratory at the Health Sciences Centre begins.

January 29, 2006: A spokeswoman for Eastern Health confirms to *The Independent* the retest results are in — but declined to make a public statement until all patients had been contacted.

"I think as soon as they knew that something was wrong, they should have told us immediately," filmmaker and breast cancer survivor Gerry Rogers told *The Independent*. "They should have done it immediately and explained what they did and didn't know, because we're not children. We're health-care consumers, and this is a system that we all own."

February 5, 2006: A follow-up story in *The Independent* reports on what appears to be the first attempt by a breast cancer patient to sue Eastern Health over the ER/PR test results.

A lawyer filed a statement of claim on behalf of Michelle B. Hanlon of Mount Pearl, alleging the cancer that cost her both breasts and later spread to her lungs, liver and brain could have been stopped or slowed if she had received the correct ER/PR test result.

Although more lawsuits are predicted, an Eastern Health spokesperson confirms, "as of right now at this moment in time, (Hanlon's) is the only lawsuit that I'm aware of."

February-May 2006: Armed with all the retest results, the tumour board makes a "concentrated effort ... to review results, write recommendations and conduct disclosures," according to Eastern Health. The organization allows the subsequent six months to offer all patients an opportunity to discuss with their physicians.

"My clients feel there are many women out there who are upset and feel that they'd like to do something legally or they'd like to have a remedy or they'd like to know what happened."

Myrtle Lewis

July 30, 2006: *The Independent* publishes a story about Myrtle Lewis, a breast cancer survivor, and her lawyer, Ches Crosbie. In the late-'90s, Lewis had both breasts and 11 lymph nodes removed, and underwent months of chemotherapy, which she says stripped her of energy, compromised her immune system, and left her sensitive to sunlight and many chemicals.

On July 5, she was contacted by the hospital and went in for a meeting. She was told medical staff had determined her cancer was "in situ," a less invasive and more localized form of breast cancer than her original diagnosis. Her specimens were among the hundreds that were retested.

Lewis joined a number of other women who are part of a class action lawsuit against Eastern Health, filed by Crosbie.

"My clients feel there are many women out there who are upset and feel that they'd like to do something legally or they'd like to have a remedy or they'd like to know what happened," he says.

"It's a problem with pathology and quality control in pathology. We're arguing that there effectively wasn't any."

Oct. 13, 2006: Ches Crosbie files papers asking for certification as a class. At least 39 women have signed on to be part of the suit.

November 2006: Eastern Health completes its quality review process.

Dec. 11, 2006: For the first time in more than a year, Eastern Health representatives speak to the media. A technical briefing is provided, as well as a tour of the immunohistochemistry lab.

Oscar Howell, vice-president of medical services says 939 negative tests were sent to Mt. Sinai for retesting. Although the conversion rate is not released, he does state that, after all files had been reviewed, 117 patients "had been identified as requiring treatment changes." In some cases, a changed ER/PR result was the cause of the change; in other cases, there were other factors involved.

Dec. 15, 2006: The defendant's (Eastern Health) materials are due to be filed in court. A date will then be set for the argument to determine if the case will be certified as a class action and proceed as such.

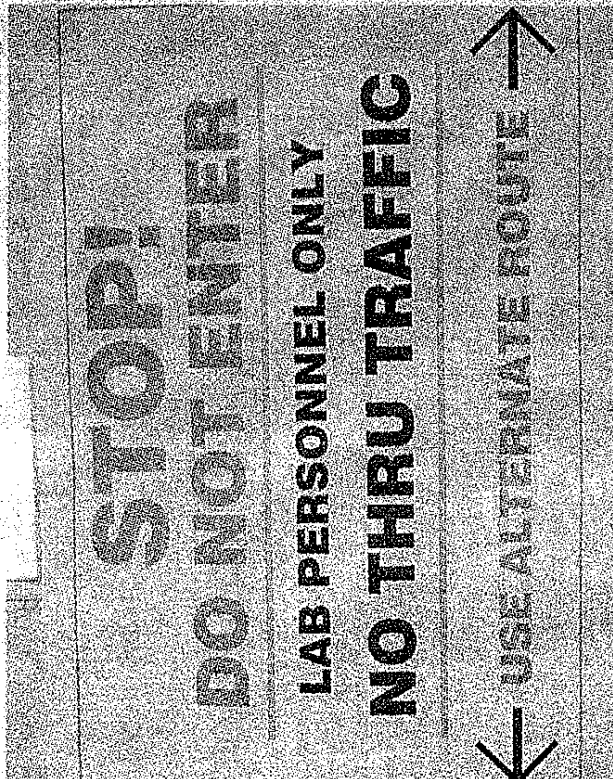
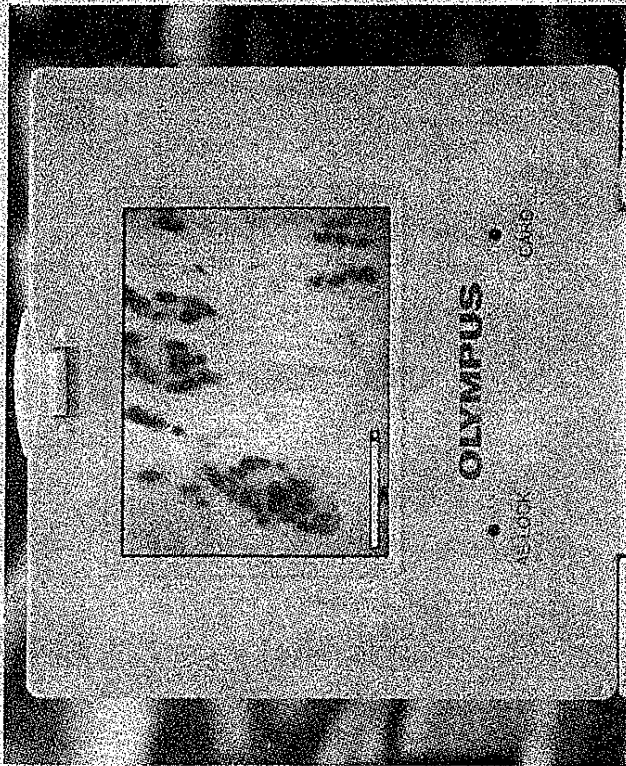
— Stephanie Porter



Dr. Nash Denic



Myrtle Lewis



A tissue sample is taken from a Harris subject.

