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To: "Tansy Mundon" <TansyMundon@gov.nl.ca>
Date: 16/05/2007 4:43:06 pm
Subject: FW: ER/PR MEdia Coverage

Old email around the time of the media briefing. Note that almost all the reporters reference the fact that we will not reveal how many women had a false report, only that 117 had treatment changes. In the briefing, this obviously came up. We were asked by Mark Quinn and others if there were more than 117 women whose test results changed and we did tell them yes, but that the # was not relevant or available to provide due to the pending litigation. Here's the prepared q and a on this issue, which as I recall we stuck to like glue:

Q9. What is the rate of error? How many people converted?

A9. Up to this point, our focus has been on making treatment changes, where appropriate, and 117 individuals have experienced treatment changes.

Some of these changes are because of a conversion in their ER/PR test result from negative to positive; some because the definition of "negative" has changed; some because of where patients are today with their disease - there are multiple factors involved.

Now that legal proceedings have been initiated, we will have to allow the legal process to determine if in fact error has occurred.

The numbers of individual conversions are not relevant and turn the process into a "numbers game." For example, some people have minor conversions that did not impact upon whether they would be considered suitable for hormonal therapy. Some individuals converted, but upon review of their treatment plan it was discovered that for other clinical reasons they were already receiving tamoxifen.

What is relevant is the number of people whose care may change as a result of the process, and that was 117.

Susan Bonnell

Director, Strategic Communications

709-777-1426 (1338)

From: Leona Barrington
Sent: Tuesday, December 12, 2006 5:16 PM
To: George Tilley; Oscar Howell; Kara Laing; Nebojsa Denic(HCCSJ);
Heather Predham; Terry Gulliver; Sharon Smith; Susan Bonnell;
'dboone@smss.com'
Cc: Michelle Gregory; Denise Dunn; Joyce Penney; Elizabeth Strange
Subject: ER/PR MEdia Coverage
Importance: High

Hello everyone,

Attached and below you'll find the media coverage from the last 24 hours on ER/PR. All in all no real surprises. Deanna Stokes-Sullivan from the Telegram provided the most accurate coverage. There were some "inaccuracies" in the other reports which I believe we addressed during the interviews today with CBC radio and TV, NTV and The Independent. The most "out of sync" report was aired yesterday by Vic Adhopia, CBC's National Radio reporter which also appears on CBC's web site. I called Vic today and left messages inviting him in to interview Dr. Howell and Dr. Laing in an attempt to clarify some of the things mentioned in his news report - but I did not hear back from him.

I will send along further coverage as it becomes available. If you have any questions or concerns, feel free to give me a call.

Cheers.

Media Headlines:

VOCM RADIO OPEN LINE Tuesday, December 12, 2006

EASTERN HEALTH RE; HIGH QUALITY PATIENT CARE: Host Preamble - Eastern Health says it's implemented a new means of insuring high quality patient care re; improving their quality management program and seeking a full accreditation for the entire laboratory facility of eastern health. This comes after failed testing for breast cancer. AIRED: 09:07 AM DURATION:

02:00 REPORTER: RANDY SIMMS

VOCM RADIO NEWS AT 7:45AM Tuesday, December 12, 2006 (ATTACHED)

NEW MEASURES FOR HEALTHCARE STANDARDS: Eastern Health says it has implemented new means of ensuring high standard patient care. ["Minnie", NightLine caller] AIRED: 07:53 AM DURATION: 01:30 REPORTER: PHELAN / GALLANT

CBC RADIO NEWS AT 7:00AM Tuesday, December 12, 2006

RESULTS OF REVIEW: Eastern Health should release the results of a review today concerning estrogen and progesterone receptor testing in breast cancer patients. [Eastern Health; Health Sciences Centre;STATION: RADCOAST | AIRED: December 12, 2006 at 06:01 AM | DURATION: 00:27

| ANCHOR: Kerry Hodder | ID: AAL655

VOCM NIGHT LINE Monday, December 11, 2006

LABORATORY REVIEW: Host preamble- Word is expected tomorrow on a study from Eastern Health on its review of estrogen and progesterone receptor testing in Breast Cancer patients at the Health Sciences Centre since 1997. Dr. Oscar Howell with medical services at eastern health says they sent 939 negative tests to Mount Sinai Laboratory in Toronto for review.

Results from 117 patients by a panel of oncologists, pathologists and surgeons, indicate they needed treatment changes. Breast Tumor samples are tested for estrogen and progesterone receptors to determine if hormonal therapy may be a treatment option. Howell says the patients have been told of a change in their test results, and they have met to determine further treatment options. However he says further information will not been released at this time, pending a class action lawsuit. Testing is expected to be reinstated at the Health Sciences centre in the coming year. AIRED:08:10 PM DURATION: 03:00 REPORTER: LINDA SWAIN

CBC RADIO EVENING NEWS AT 5:00PM Monday, December 11, 2006 (Transcript attached)

ANSWERS FOR BREAST CANCER PATIENTS: There are finally more answers about tests for breast cancer patients in this province. Today, Eastern Health released some new information. ["Mark Quinn", reporter; "Peter Dawe", Cancer Society] AIRED: 5:00 PM DURATION: 01:45 REPORTER: DAVE BARTLETT

VOCM RADIO NEWS AT 5:30PM Monday, December 11, 2006 (Transcript attached)

BREAST CANCER TESTING REVIEW: Word expected tomorrow on a study from Eastern Health on its review of estrogen progesterone receptor testing in breast cancer patients at the Health Sciences Centre since 1997.
["Renell LeGrow", reporter] AIRED: 5:30 PM DURATION: 01:00 REPORTER: CARLA FOOTE

CBC TV HERE & NOW AT 6:00 PM Monday, December 11, 2006 (Transcript attached)

CANCER TESTS TO CONTINUE: The Eastern Health Corporation says it will resume breast cancer screening tests at its lab in St. John's next year.

The corporation suspended testing at the lab 18 months ago after problems with breast cancer screening tests. [Eastern Health;] | STATION: CBNT |

AIRED: December 11, 2006 at 06:12 PM | DURATION: 01:28 | ANCHOR: O'Neil/Crowe | ID: AAL616

NTV EVENING NEWS AT 6:00PM Monday, December 11, 2006 (Transcript attached)

4. EASTERN HEALTH'S REPORT RELEASED: A mistake in testing led to incorrect treatment for 117 women in this province suffering from breast cancer. ["Carolyn Stokes", reporter; unknown [Eastern Health;] | STATION: NTV | AIRED: December 11, 2006 at 06:06 PM | DURATION: 02:28 |

ANCHOR/REPORTER: HUTTON/CARTER/CAROLYN STOKES | ID: AAL610

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Product Summary:

ANSWERS FOR BREAST CANCER PATIENTS: There are finally more answers about tests for breast cancer patients in this province.

Monday, December 11, 2006 05:00PM Item # 01

CBC Radio St. John's

Standing Order: NO

ANSWERS FOR BREAST CANCER PATIENTS: There are finally more answers about tests for breast cancer patients in this province.

Monday, December 11, 2006 05:00PM Item # 01

CBC Radio St. John's

DAVE BARTLETT: There are finally more answers about tests for breast cancer patients in this province. More than eighteen months ago, Eastern Health identified a problem at its lab. Some women got the wrong results from hormone receptors tests; that means some of them may have received the wrong treatment. Today, Eastern Health released some new information. As Mark Quinn reports, a surprisingly large number of women weren't getting the treatment they should have been.

MARK QUINN: The lab at the Health Sciences Centre in St. John's does millions of tests every year but it stopped doing hormone receptor tests about eighteen months ago. That's when Eastern Health learned that some of the results it was giving breast cancer patients were wrong. It told some patients that their hormone receptor tests were negative when another lab found they were positive. A positive results means a cancer patient may get a hormone blocking treatment that could improve their chance of survival. For the first time, Eastern Health is saying how many women have had their breast cancer treatment changed because of the retesting. It's a large number – one hundred and seventeen. Peter Dawe is with the Canadian Cancer Society. He wants to know how many women who since died also had the wrong results.

PETER DAWE: What we're not seeing, still, is a full explanation of, of the numbers of people that were affected overall and, you know, some idea of what actually went wrong with the process.

MARK QUINN: Eastern Health is facing a class action suit. Health authorities aren't saying if the problem was caused by human error or technical problems. Hormone receptor tests still aren't being done in this province. Eastern Health hopes to begin doing them here again early next year. Mark Quinn, CBC News, St. John's.

117 N.L. cancer patients receive belated hormone treatment

Last Updated: Monday, December 11, 2006 | 5:33 PM NT

CBC News

More than 100 patients in Newfoundland and Labrador failed to receive a hormone treatment for breast cancer because of a screening problem, health officials said Monday.

The patients were initially disqualified from treatment because of problems with the tests used to determine eligibility.

After tissue samples were retested, 117 patients were started on the hormone treatment they should have received earlier.

Since last year, Toronto's Mount Sinai Hospital has been retesting samples from about 900 patients in St. John's who were initially tested between 1997 and 2005. As a result of the retesting, 117 patients who had been denied treatment earlier are now receiving it.

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.

The tests are given to women who have been treated for breast cancer in the past. Those who are considered "cancer-free" are still tested frequently in the years following their therapy.

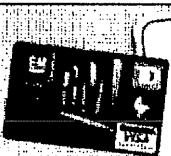
Because of a potential lawsuit, provincial health officials refused to explain if the discrepancy resulted from human error or from new methods of interpreting test results.

Officials also would not say if any patients who were mistakenly denied hormone treatment had died, or were needlessly given mastectomies when they could have been treated with drugs.

"Not receiving this treatment could very well mean a life and death issue for people going through the process," said Peter Dawe, director of the Newfoundland and Labrador chapter of the Canadian Cancer Society.

The lack of disclosure raises questions, said Dawe, about what the problem is and how it can be fixed.

Health officials in Newfoundland and Labrador hope to resume their own hormone testing in the near future, though they can't say when.



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Eastern Health Makes Changes

December 12, 2006

Eastern Health says it has implemented new means of ensuring high standard patient care including improving a Quality Management Program and seeking accreditation for the entire laboratory. This after some failed testing for breast cancer. Breast Tumor samples are tested for estrogen and progesterone receptors to determine if hormonal therapy may be a treatment option. Over 100 women did not receive proper treatment because of a screening problem. 117 patients were identified as requiring treatment changes by a panel of oncologists, pathologists and surgeons. Some of the women have launched a class action suit against the corporation. On VOCM Night Line with Linda Swain, one of the women affected by the screening problem was not enthused by the latest development. Minnie said it's very difficult to get information from the corporation. Patients who have been notified of a change in result have met with their treating physicians to determine their current treatment options. Meantime, Eastern Health is expected to reinstate testing at the Health Sciences Centre in the coming year.

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ER/PR coverage

CBC TV

Monday, December 11, 2006

Chris O'Neil Yates:

The Eastern Health corporation says it will resume breast cancer screen tests at its lab in St. John's next year. The corporation suspended testing at the lab 18 months ago after problems with breast cancer screening tests. Today, Eastern Health gave reporters a tour of the lab but they're still not confirming how many of the tests show false results.

From 1997 to 2005, Eastern Health conducted 2,760 tests on women with breast cancer to determine their estrogen levels, that's to assess whether they needed hormonal therapy such as Tamoxifin. After they discovered problems, 939 samples had to be retested at Mount Sinai in Toronto. Because of a class action lawsuit, Eastern Health will not say how many of those samples had a false result. Eastern Health will only say that 117 patients required treatment changes. The corporation also won't say how many of these patients are part of the retesting or how many people who passed away had the initial false test. Eastern Health says it's putting quality assurance measures in place to restore public confidence before it resumes this test and says it doesn't know how the false results happened.

NTV

December 11, 2006

Glen Carter: A mistake in testing led to incorrect treatment for 117 women in this province suffering from breast cancer. That is the conclusion of an 18 month investigation by Eastern Health. Today, it released the results of independent retesting of thousands of breast cancer samples going back a decade. For most, the mistake made no difference but for dozens, it made a huge impact in the decisions that were made to save their lives. NTV's Carolyn Stokes reports.

Carolyn Stokes:

Today, Eastern Health held a technical briefing and laboratory tour for the media to shed some light on the complicated process of testing breast cancer samples for hormone receptivity.

Dr. Denic:

I don't know if it will make you more confused that you know of, or at least try to make you understand what we do and why the thing is the way that it is but every single year we are going to do better. Science is going to do better.

Carolyn Stokes: In May of 2005, after the laboratory process changed from semi-automated to fully automated, it was discovered that the estrogen progesterone or ER/PR tests being conducted at the Health Sciences Centre were giving incorrect results. Those results affected whether a patient received certain treatment drugs such as Tomoxifin.

Dr. Denic: This lab is working for the patient. I guarantee you. Every single person working over there is working for the patient and every single person in this lab had great concerns in regard to this issue because there's no person in this lab that his or her family has been stricken by cancer.

Carolyn Stokes: Eastern Health referred almost 3000 samples dating back to 1997 and sent over 900 to Mount Sinai Hospital to be retested. As a result, 117 women were told they were given inappropriate cancer treatments. That number doesn't include the amount of false results or patients who are now deceased. Eastern Health says that number can't be released due to a class action lawsuit that has been launched against them.

Dr. Denic: We have excellent mechanism in place that if anything goes wrong, down the road, we can catch.

Carolyn Stokes: The laboratory has stopped ER/PR testing during an external review of their system and Eastern Health says new quality controls have been implemented. The testing is scheduled to begin again in two months time. Carolyn Stokes, NTV News.

HEALTH
JOURNAL OF CANADIAN MEDICAL NEWS

Treatments change after cancer files reviewed

By DIANA STOKES SULLIVAN
Staff Writer, The Telegram
THE TELEGRAM

Treatment changes have been recommended for 117 Eastern Health authority patients, arising from a review and retesting of all breast tumour samples that were initially tested at the Health Sciences Centre between 1997 and 2005.

However, because of a pending class action lawsuit, Eastern Health officials won't say how many samples have converted, in the latest round of testing, from negative to positive for estrogen and progesterone receptors.

This testing is used to determine if a patient's cancer cells can be stimulated by hormones. Patients who test positive may be offered drugs that block this action.

In a technical briefing for the news media Monday, Dr. Oscar Howell, Eastern Health's vice-president of medical services, explained that the health board became aware in May of last year that a tissue sample from

one patient, which initially tested negative in 2002 for hormone receptors, converted to a positive result after a second test using new equipment.

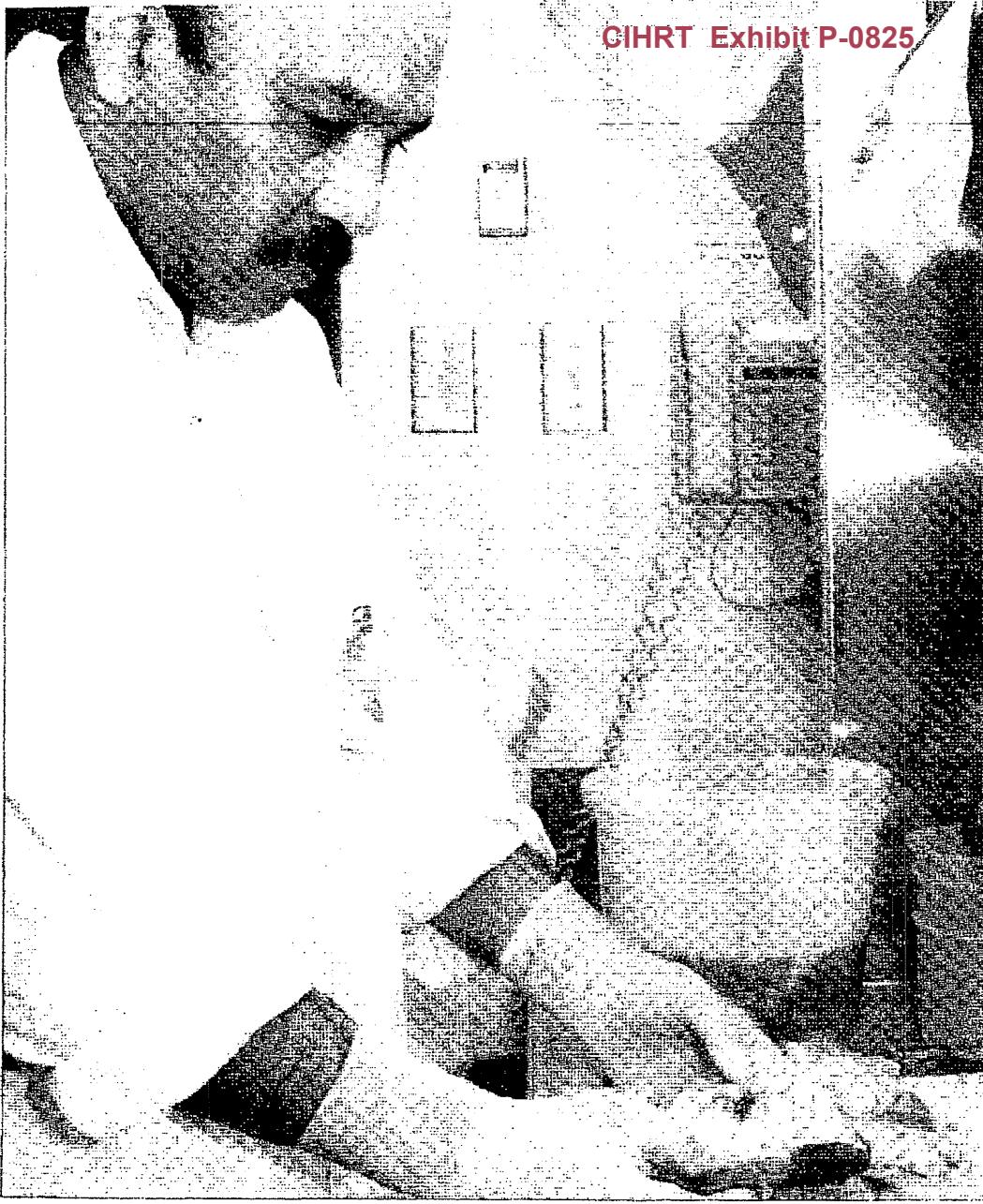
Dr. Kara Laing, Eastern Health's cancer program clinical chief, said the patient's situation made her doctors question whether she might be positive and the hormone test was reordered.

The initial testing was conducted using a semi-automatic Dako system, involving a more complex process and multiple steps.

In April 2004, a new automatic Ventana system was installed for use in the immunohistochemistry laboratory. The second test was conducted using this new equipment.

Representatives from the laboratory program met with oncologists to discuss the new result and a decision was made to test five more negative patients, whose tissue samples also converted to positive.

See MORE, page A4



Dr. Chandrakanth Annaiah, a fifth-year pathology intern, dissects a kidney tumour in the immunohistochemistry laboratory at the Health Sciences Centre. — Photo by J.P. Gibbons/The Telegram

CIHRT Exhibit P-0825

More tests ... Continued from page A1
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From there, decisions were made to do further testing, going back as far as 1997.

From 1997 to 2005, there were 2,760 estrogen/progesterone receptor tests conducted at the Health Sciences Centre. Out of that total, 939 were originally negative.

It was decided to send all of these 939 samples to the Mount Sinai Laboratory in Toronto for an independent review.

Eastern Health received the last test results from Mount Sinai in February 2006.

Laing said while the retesting has resulted in recommended treatment changes for 117 patients, some of these women might have already been taking the commonly prescribed Tamoxifen.

But, "If seven years had gone by, we wouldn't recommend a treatment change," she added.

In some cases, Laing said, treatment changes may be recommended, simply because of the review of patient files rather than the second test results.

Laing explained that there are two parts to treatment for breast cancer. The first stage is surgery and radiation and the second part is the drug treatment and systemic treatment.

There's no doubt that all of these women had breast cancer, Laing said. Hormone testing simply helps determine the mode of treatment to try and prevent the cancer from returning.

When a cancer tumour is removed, Laing said, there could be cells left behind that might be receptive to hormone stimulation. Drugs like Tamoxifen and now some of the newer medications block that action.

Howell said it's difficult to assign blame when, in addition to new technology being available for hormone testing, the definition of what constitutes a positive lab result has also changed in recent years.

At one point, he said, a positive diagnosis was made when 30 per cent of

cells on a slide took up the stain used to identify hormone receptors. Later that was lowered to 10 per cent and some labs even interpret one per cent as enough for a positive result.

In some cases even when a patient tests positive, Howell said, they might opt not to take Tamoxifen because of adverse side effects, such as a higher risk of uterine cancer.

Laing said if a patient had a history of a blood clot, they also wouldn't be considered a candidate for Tamoxifen.

The newer aromatase inhibitors now offer an alternative therapy, but Laing said, they've only been available in the last few years.

Besides collecting, sending, retesting and reviewing all samples, Eastern Health says it has also conducted an extensive quality review within its immunohistochemistry laboratory.

Howell said this quality review was completed in November, but much of the information is "protected information." He said it was important that people felt free to be open with their comments.

Howell and a new chief pathologist for the laboratory program, Dr. Nash Denic, have worked on the results of the review and Eastern Health says it has established a centre of excellence for breast cancer pathology and is "generally prepared" for the continuation of estrogen/progesterone testing.

Denic said Eastern Health is the only health board that he knows of that has undertaken such an extensive retesting of false negatives. Ultimately, he said, the goal has been to improve the standard of practice.

It's not yet certain when estrogen/progesterone testing will resume at the Health Sciences Centre. But Howell said, Eastern Health wants to ensure that all patients will receive the best treatments possible.