

From: Elizabeth Matthews
To: Andrea Nolan; Brian Crawley; Carmel Turpin; Don Burrage; Robert Thompson; Sandra Barnes; Tansy Mondon
Date: Tue, May 22, 2007 11:48 AM
Subject: Fwd: Re: Draft news release

I don't recall seeing an itemized email.

em

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>>> Tansy Mondon 5/22/2007 11:44:36 AM >>>
A quote has been added to the end. Do you want another quote on quality.
I thought we addressed your questions in a previous email with an itemized list.

>>> Elizabeth Matthews 5/22/2007 11:41 AM >>>
The first two comments in my original email have still not been addressed. There is no further quote from the minister; and did Eastern Health indeed contact all of those patients directly? Because this is contrary to what we were told. Can someone please clarify.

em

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>>> Tansy Mondon 5/22/2007 11:33:32 AM >>>
Revised attached

Tansy

Health and Community Services
May 22, 2007

Government to Undertake a Commission of Inquiry on Estrogen and Progesterone Receptor Testing for Breast Cancer Patients

In order to maintain confidence in the provincial estrogen and progesterone receptor (ER/PR) breast cancer testing system at Eastern Health, the Honourable Ross Wiseman, Minister of Health and Community Services, today announced that the Provincial Government will undertake a Commission of Inquiry on estrogen and progesterone receptor testing for breast cancer patients.

On Friday, Eastern Health CEO George Tilley apologized for the confusion that has ensued over this issue

and stated that 'at no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for ER/PR' and that 'Eastern Health has acted and will continue to act in the best interest of our patients.'

"Government recognizes it is of the utmost importance for those directly involved and the general public to understand what happened to ensure that this situation does not reoccur," said Minister Wiseman. "Through an independent review, we will endeavor to get those answers."

A Commission of Inquiry will be established by the Provincial Cabinet under the Public Inquiries Act, 2006. Cabinet will appoint a Commissioner, set the terms of reference for the inquiry and authorize an appropriate budget. Once the Commissioner's report is completed, it will be submitted to the Minister of Health and Community Services and will be released publicly.

The review will address six key questions:

1. What went wrong with the ER/PR tests that resulted in a high rate of conversions when re-tested?
2. Why was the problem with the tests not detected until 2005? Could it have been detected at an earlier date? Were the testing protocols during that period reasonable and appropriate?
3. Once detected, did the responsible authorities respond in an appropriate and timely manner to those categories of people who needed re-tests and those who were being tested for the first time?
4. Once detected, did the responsible authorities communicate in an appropriate and timely manner with the general public about the issues and circumstances surrounding the change in test results and the new testing procedures?
5. Are the testing systems and processes currently in place reflective of "best practice"?
6. Does Eastern Health currently employ an effective quality assurance system to provide maximum probability that the testing problems will not reoccur?

The Commissioner will provide recommendations as necessary and appropriate to address the questions for the inquiry as identified above. The Minister will announce further details regarding the Commission of Inquiry, including the appointment of a commissioner.

Minister Wiseman added, "I look forward to receiving the commissioner's report which will answer the many questions that have arisen with respect to this issue."

- 30 -

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Backgrounder - ER/PR Testing for Breast Cancer Patients

- This issue is not about breast cancer screening. At no time has there been a question of accuracy of mammograms or biopsy results to diagnose breast cancer.
- Estrogen and progesterone testing (ER/PR) takes place after a breast cancer diagnosis to determine whether cancer cells have estrogen or progesterone receptors. Breast cancers that are either ER-positive or PR-positive (or both) may respond to hormone therapy, such as the drug Tamoxifen. Hormonal therapy, chemotherapy and radiation are considered to be adjuvant therapies. The aim of adjuvant therapy is to decrease breast recurrence rates and improve overall survival rates. Adjuvant therapies are generally additional treatments given after potentially curative surgery.
- Eastern Health first became aware of a problem with ER/PR test results in May 2005 and immediately conducted an internal review. In July 2005 it made a decision to retest all negative ER/PR tests done between May 1997 and August 2005 to ensure that if there was one patient who could benefit

as a result of a change in their test result and subsequent treatment change that it was important that this be done. Eastern Health also suspended their own testing at that time.

- The process to retest and conduct external and internal reviews in the lab took about one year to complete. Once test results came back, the results were assessed to determine if a recommended treatment change was necessary. The assessments were conducted by a panel of experts in cancer care, including oncologists, pathologists and surgeons. The first test results were received by Eastern Health in October 2005. All test results were received by February 2006.

- There were a total of 939 patients with ER negative reports. Of the 763 patients reviewed, 317 patients had a change in result. Of that number, 117 of the patients had a resulting change in treatment. A further 176 patients, of the total 939, originally reported as negative are deceased.

- Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:

- o That their tissue had been retested and there was no change in the original results;

- o That their tissue had been retested and that Eastern Health was recommending a change in their treatment; or

- o That although there was a change from their original test result, no change in treatment was recommended.

- There was full disclosure to patients and their families once test results became available.

Unfortunately, test results came back at different times and there was a delay in the retesting process which led to some patients feeling they were not informed in a timely fashion. Ultimately, Eastern Health's primary concern was notifying all affected individuals.

- Eastern Health held a media briefing in December 2006. At the time the focus was on the 117 patients who had a change in test result and a change in treatment plan. Unfortunately, the media were not provided with the number of test results that had changed (317).

- Eastern Health has committed to retest results for the 176 patients who are deceased and to ensure that all patients' families are contacted for follow up.

- Eastern Health apologized on Friday for the confusion created by not disclosing all of the information to the media in December. Although the media were not informed, the 317 patients who were directly impacted were informed of their individual circumstances.

- Eastern Health has implemented a number of measures to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training. In addition, as a measure of quality control, a random sample of tests are sent to Mount Sinai to ensure the accuracy of Eastern Health test results. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007.

>>> Elizabeth Matthews 5/22/2007 11:17 AM >>>

Looks like the same release as the original.....

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>>> Tansy Mundon 5/22/2007 11:03:06 AM >>>

Oops, forgot attachment.

Health and Community Services

May 22, 2007

Government to Undertake a Commission of Inquiry on Estrogen and Progesterone Receptor Testing for Breast Cancer Patients

In order to maintain confidence in the provincial estrogen and progesterone receptor (ER/PR) breast cancer testing system at Eastern Health, the Honourable Ross Wiseman, Minister of Health and Community Services, today announced that the Provincial Government will undertake a Commission of Inquiry on estrogen and progesterone receptor testing for breast cancer patients.

On Friday, Eastern Health CEO George Tilley apologized for the confusion that has ensued over this issue and stated that 'at no time did Eastern Health withhold any personal information from any of the patients impacted by our decision to retest for ER/PR' and that 'Eastern Health has acted and will continue to act in the best interest of our patients.'

"Government recognizes it is of the utmost importance for those directly involved and the general public to understand what happened to ensure that this situation does not reoccur," said Minister Wiseman. "Through an independent review, we will endeavor to get those answers."

A Commission of Inquiry will be established by the Provincial Cabinet under the Public Inquiries Act, 2006. Cabinet will appoint a Commissioner, set the terms of reference for the inquiry and authorize an appropriate budget. Once the Commissioner's report is completed, it will be submitted to the Minister of Health and Community Services and will be released publicly.

The review will address seven key questions:

1. What went wrong with the ER/PR tests that resulted in a high rate of conversions when re-tested?
2. Why was the problem with the tests not detected until 2005? Could it have been detected at an earlier date? Were the testing protocols during that period reasonable and appropriate?
3. Once detected, were appropriate, effective and timely actions implemented to ensure the best possible treatment for categories of people who needed re-tests and for people who were being tested for the first time?
4. Once detected, did the responsible authorities communicate in an appropriate and timely manner with all categories of people who needed re-tests?
5. Once detected, did the responsible authorities communicate in an appropriate and timely manner with the general public about the issues and circumstances surrounding the change in test results and the new testing procedures?
6. Are the testing systems and processes currently in place reflective of "best practice"?
7. Does Eastern Health currently employ an effective quality assurance system to provide maximum probability that the testing problems will not reoccur?

The Commissioner will provide recommendations as necessary and appropriate to address the questions for the inquiry as identified above. The Minister will announce further details regarding the Commission of Inquiry, including the appointment of a commissioner.

Media Contact:

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Background - ER/PR

- This issue is not about breast cancer screening. At no time has there been a question of accuracy of mammograms or biopsy results to diagnosis breast cancer.
- Estrogen and progesterone testing (ER/PR) is a test taken once a breast cancer diagnosis has been made to determine whether cancer cells have estrogen or progesterone receptors. Breast cancers

that are either ER-positive or PR positive (or both) may respond to hormone therapy, such as the drug Tamoxifen. Hormonal therapy, chemotherapy and radiation are considered to be adjuvant therapies. The aim of adjuvant therapy is to decrease breast recurrence rates and improve overall survival rates. Adjuvant therapies are generally additional treatments given after potentially curative surgery.

- Eastern Health first became aware of a problem with ER/PR test results in May 2005 and immediately conducted an internal review. In July 2005 they made a decision to retest all negative ER/PR tests done between May 1997 and August 2005 to ensure that if there was one patient who could benefit as a result of a change in their test result and subsequent treatment change that it was important that this be done. They also suspended their own testing at that time.
- The process of retesting and to conduct external and internal reviews in the lab took about one year to complete. Once test results came back, the results were assessed to determine if a recommended treatment change was necessary. The assessments were conducted by a panel of experts in cancer care, including oncologists, pathologists and surgeons. The first test results were received by Eastern Health in October 2005. All test results were received by February 2006.
- There were a total of 939 patients with ER negative reports. Of the 763 patients reviewed, 317 patients had a change in result. Of that number, 117 of the patients had a resulting change in treatment. A further 176 patients, of the total 939, originally reported as negative are deceased.
- Eastern Health contacted each patient who was affected by the ER/PR test review or their family physician to make sure they received all the information and support they required. They were told either one of three things:
 - o That their tissue had been retested and there was no change in the original results;
 - o That their tissue had been tested and that EH was recommending a change in their treatment; or
 - o That although there was a change from their original test result, no change in treatment was recommended.
- There was full disclosure to patients and their families once test results became available. Unfortunately, test results came back at different times and there was a delay in the retesting process which led to some patients feeling they were not informed in a timely fashion. Ultimately, Eastern Health's primary concern was notifying all affected individuals.
- Eastern Health held a media briefing in December 2006. At the time the focus was on the 117 patients who had a change in test result and a change in treatment plan. Unfortunately, the media were not provided with the number of test results that had changed (317), which has resulted in the source of much confusion.
- Eastern Health has committed to retest results for the 176 patients who are deceased and to ensure that all patients' families are contacted for follow up. Unfortunately, it is not known how many of these patients may have benefited from hormonal therapy.
- Eastern Health apologized on Friday for the confusion created by not disclosing all of the information to the media in December. Although the media were not informed, the 317 patients who were directly impacted were informed of their individual circumstances.
- Eastern Health has implemented a number of measures to provide a high standard of ER/PR testing for new breast cancer patients. These measures include a quality management program, seeking national accreditation for the laboratory and ensuring all technologists and pathologists receive special training. In addition, as a measure of quality control, a random sample of tests are sent to Mount Sinai to ensure accuracy of the accuracy of Eastern Health test results. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007.

CC: John Abbott; Moira Hennessey