

From: Tansy Mundon
To: Abbott, John; Hennessey, Moira
Date: Mon, May 21, 2007 7:35 PM
Subject: Draft key messages for your review

Key Messages – ER/PR

- Government is very sympathetic to the individuals impacted by this situation. We regret that the past two years has been a stressful period for some patients and their families.
- This issue is not about breast cancer screening. Estrogen and progesterone testing (ER/PR) is a test taken once a breast cancer diagnosis has been made. It is used to determine if a breast cancer patient might benefit from hormonal therapy. At no time has there been a question of accuracy of mammograms or biopsy results to diagnosis breast cancer.
- Eastern Health first became aware of a problem with 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 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 and pathologists. 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.
- Eastern Health contacted each patient who was affected by the ER/PR test review, making sure they received all the information and support they required. Patients 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 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 with 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. The affected individuals received full disclosure regarding their results.
- 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 but no 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 have deceased and to ensure that all patient's families are contacted for follow up. Unfortunately, it is not known how many of these patients may have benefited from hormonal therapy.
- Eastern Health has apologized for the confusion created by not disclosing all of the information to the media in December.
- 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, some tests are sent to Mount Sinai to ensure accuracy of results over time. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.
- Government believes there was no deliberate attempt to withhold information and that Eastern Health's first priority was the patient. However, we also recognize the importance of understanding what happened and we are committed to undertaking a commission of inquiry to ensure that we get those answers.

CC:

Mundon, Tansy

Key Messages – ER/PR

- Government is very sympathetic to the individuals impacted by this situation. We regret that the past two years has been a stressful period for some patients and their families.
- This issue is not about breast cancer screening. Estrogen and progesterone testing (ER/PR) is a test taken once a breast cancer diagnosis has been made. It is used to determine if a breast cancer patient might benefit from hormonal therapy. At no time has there been a question of accuracy of mammograms or biopsy results to diagnosis breast cancer.
- Eastern Health first became aware of a problem with 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 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 and pathologists. 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.
- Eastern Health contacted each patient who was affected by the ER/PR test review, making sure they received all the information and support they required. Patients were told either one of three things:
 - That their tissue had been retested and there was no change in the original results;
 - That their tissue had been tested and that that EH was recommending a change in their treatment; or
 - That although there was a change from their original test result, no change in treatment was recommended.
- There was full disclosure with 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. The affected individuals received full disclosure regarding their results.
- 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 but no 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 have deceased and to ensure that all patient's families are contacted for follow up.

Unfortunately, it is not known how many of these patients may have benefited from hormonal therapy.

Eastern Health has apologized for the confusion created by not disclosing all of the information to the media in December.

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, some tests are sent to Mount Sinai to ensure accuracy of results over time. Eastern Health resumed ER/PR testing in St. John's on February 1, 2007. We are confident that Eastern Health has implemented the appropriate new measures to ensure the highest standard of care for breast cancer patients.

- Government believes there was no deliberate attempt to withhold information and that Eastern Health's first priority was the patient. However, we also recognize the importance of understanding what happened and we are committed to undertaking a commission of inquiry to ensure that we get those answers.