

From: Tansy Mundon
To: Matthews, Elizabeth; Nolan, Andrea
Date: Tue, Dec 12, 2006 12:34 PM
Subject: BN for Premier on ER/PR

Elizabeth/Andrea,
For the Premier's information. This issue is in the media today.

Tks,
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Question and Answer Briefing Note
Department of Health and Community Services

Title: ER/PR Testing, St. John's

Issue: A mistake in testing may have led to incorrect treatment for 117 women in this province suffering from breast cancer. Not receiving proper treatment could mean a life and death issue for women going through cancer.

Anticipated Questions:

- As Minister of Health and Community Services, have you lost confidence in the physicians and managers at Eastern Health responsible for breast cancer screening?
- Why has it taken more than one year for Eastern Health to go public and release the results?
- What is the rate of error?
- When will breast cancer screening test resume at the laboratory in St. John's?

Key Messages:

- Providing quality health services to the people of this province is a priority for our Government. We regret that this may have been a stressful period for patients and their families. We are confident that Eastern Health is dedicated to improving the system and has implemented new means of ensuring a high standard of care for breast cancer patients.
- Eastern Health acted quickly and initiated retesting of ER/PR test results when the problem was discovered in May 2005. Arrangements were put in place for an independent laboratory to review the test results and complete ongoing work. The health authority took the time it felt was necessary to review the test results from Mount Sinai and conduct an extensive quality review of the laboratory prior to releasing the findings to the public.
- Eastern Health has been upfront and open with patients as soon as information about their personal situations was available. The organization has acted in what it determined to be in the best interest of its patients.
- Test samples for 939 breast cancer patients between 1997 and 2005 were retested. One hundred and seventeen (117) patients had recommended changes in their treatment plans as a result of review by a panel of experts. There were multiple factors involved. Since legal proceedings have been initiated, we will have to allow the legal process to determine if in fact error has occurred.
- Eastern Health expects to begin testing of new patients in St. John's in the new year.

Other Suggested Response(s):

- Eastern Health has put a number of measures in place to reduce the risk of a similar problem occurring in the future. While this has been an unfortunate event, we are focused on ensuring patients have every treatment option that may be available to them and on addressing system issues that arise.

- Eastern Health has implemented or in the process of implementing all recommendations from the external reviews. A dedicated laboratory has been identified to perform the ER/PR, testing with 3 designated technologists, a lab medical director, and a dedicated cutter and all staff received specialized training. A centre of excellence for breast cancer cases has been established so that examination and reporting will be directed to a dedicated group of pathologists. The dedicated lab has established a Quality Management Program and the accreditation process has been initiated for the entire laboratory department.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. The tests examine hormone receptors Estrogen (ER) or Progesterone (PR) in breast cancer cells to help physicians determine what course of treatment to follow for each patient (eg. chemotherapy, radiation).
- The chronology of the ER/PR retesting is as follows:
 - May 2005 – an oncologist discovered inconsistent test results on a patient who tested ER/PR negative in 2002 on a DAKO system and ER/PR positive in 2005 on the new VANTANA system.
 - July 2005 – decision made to retest internally all patients who were ER/PR negative from 1997 to 2004. Technology has changed over time and is more sensitive to picking up ER/PR negatives and positives.
 - Late July 2005 – decision made to arrange for an independent laboratory to complete retesting (Mount Sinai) and ongoing work.
 - August 2005 - process of collecting packaging and shipping negative test results to Mount Sinai began.
 - October 2005 – Tumor board, consisting of two oncologists, two surgeons, two pathologists, one rep from quality department and one support person, was established to review the results as they arrived back from Mount Sinai and made treatment recommendations for each patient. Patients were contacted about specimens being sent away for retesting.
 - February 2006 – the last test results were received from Mount Sinai.
 - February to May 2006 – Tumor board reviewed test results, wrote recommendations and disclosed information to patients.
 - June to November 2006 – the new chief pathologist and new VP – Medical Services established a centre of excellence for breast cancer pathology, assigned a head pathologist for immunohistochemistry and prepared to resume ER/PR testing in St. John's.
 - Late November 2006 – Eastern Health completes its quality review.
 - December 11, 2006 – Eastern Health releases outcomes of laboratory review to the public. A technical briefing was also provided to the media.
- In the review period from 1997 to 2005, there were 2760 ER/PR tests conducted at the laboratory. Nine hundred and thirty-nine (939) of these tests were originally negative and were sent to Mount Sinai for retesting. This number represents about 34% of the patients tested for breast cancer. All retesting has been completed.
- Eastern Health did not initially advise patients of the retesting and many learned

of it from the media before they were contacted by Eastern officials last Fall. Eastern intended to wait for the results before disclosing actual information to the patients instead of having to tell them that they may or may not be impacted by the review and that Eastern didn't know what this would mean for them. Eastern also did not want to unnecessarily raise alarm for individuals who may not be affected.

- The details on the test results are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Patients Requiring Treatment Changes	117
- The 939 patients included 176 individuals who are deceased. One hundred and one patients were retested and results received. There were two patients who were retested upon request. The remaining 73 will not be retested unless the families request it.
- Last Spring, the family of the late Michelle Hanlon filed a claim against Eastern Health. Ms. Hanlon tested negative on a breast tumour sample in 2000 but on retesting was found to be positive. The family claim that if the correct test result was known earlier, the appropriate treatment would have been started which would have prevented the spread of her disease, and possibly her death. Eastern has filed a statement of defence asking that the case be dismissed.
- A claim has been filed, named Verna Doucette vs. Eastern Regional Health Authority (ERHA), with the Newfoundland Supreme Court, Trial Division. Government is not named as party to the action. Ches Crosbie is representing the approximately 40 plaintiffs; Dan Boone is representing Eastern Health and Judge Carl Thompson is assigned as case management judge.
- The claim alleges faulty ER and PR testing by Eastern Health, resulting in the administration of inappropriate treatment to some cancer patients. The claim has not yet been certified as a class action. It is still in the early stages of litigation.
- Eastern Health has to file an affidavit in court by December 15, 2006. The lawyers have to file documents and case law with the court by February 9, 2007 at which time a request can be made for the court date for the hearing of the certification application.
- Eastern Health has also taken measures to address the system issues including a review by two laboratory experts from outside the province, investments in technology, recruitment of four pathology assistants, and consolidation of pathologist review of breast tissue samples. Eastern is also pursuing accreditation of the laboratory sciences.

Drafted by: Beverley Griffiths, 729-0717

Approved by: Moira Hennessey

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