

**Question and Answer Briefing Note
Department of Health and Community Services**

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

Issue: Breast cancer survivors want answers about mistakes in a breast cancer screening test. Eastern Health discovered the problem a year and a half ago and on December 12 they released outcomes of the laboratory review.

Anticipated Questions:

- Why did it take 18 months for the review to be completed?
- Have all 117 patients affected been notified?
- Were patients put in danger because of the length of time for completion of the review?
- There were 117 patients who did not receive timely cancer therapies. Are the pathologists and/or technicians at fault here?
- What has been done to ensure this will not happen again and can you give assurances to the public and particularly breast cancer patients?

Key Messages:

- We take this matter seriously and regret that this has been a stressful time for some cancer patients. This is the first opportunity to release all of the numbers as the process to collect, send, retest, review and analyze 939 tests by an expert panel. As the results were received from Mt. Sinai, individual patients were immediately contacted.
- Our first priority was to the 117 patients who had negative ER/PR results and as the results were sent back from Mt. Sinai we took all measures possible to ensure the patients were contacted. We were very up front and open with patients in one-on-one sessions. A panel of experts reviewed each of the 117 patients and recommended any changes in their treatment plans. Some of the changes are because of the conversion in their ER/PR test result from negative to positive; some because the definition of "negative" has changed and some because of where patients are today with their disease. There were multiple factors to consider.
- It is impossible to predict how the impact of this review will impact specific patients into the future. The delay in testing was only a matter of weeks or months and is unlikely to be significant. I must emphasize that in the vast majority of the cases tested and treated between 1997 and 2005, the patient's treatment was confirmed appropriate.
- All health authorities in the province employ competent and nationally recognized specialists and technicians who are dedicated to providing the highest quality care possible to our patients. Employees and physicians brought this issue forward and have been working diligently to ensure that the retesting and the quality review process have been conducted as efficiently and as effectively as possible.

- Eastern Health has implemented or in the process of implementing all recommendations from the external reviews. A designated laboratory has been identified to perform the ER/PR testing in a separate department with 3 designated technologists, a lab medical director, and a dedicated cutter and all staff received specialized training. A centre of excellence for all breast cancer cases has been established so that all 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.

Other Suggested Response(s):

- A quality review began immediately when the problem was discovered in May 2005. Eastern Health had external consultants review the method of testing for ER/PR receptors being used. The consultants' recommendations have been implemented. They returned to Eastern Health in early April this year to assess the progress and were pleased that measures were put in place to address the concerns.

Background:

- In May 2005, the laboratory at the Health Sciences Centre discovered inconsistent results in breast tumour samples. This happened when a patient who had tested ER (estrogen) and PR (progesterone) negative in 2002 on a DAKO system was retested on a new VANTANA system in 2005 and the test results were positive. The tests examine hormone receptors in breast cancer cells for ER and PR and help physicians determine what course of treatment to follow for each patient.
- Eastern Health sent 939 collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. This number represents about 27% of the patients tested for breast cancer. All retesting has been completed. **Eastern Health did not advise patients of the retesting and many learned of it from the media.**
- 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.
- CBC News reported on October 19 that forty-one women join class action bid on faulty breast cancer tests. The Independent, in an article on October 20, reported that at least 39 cancer patients have filed papers with Ches Crosbie, a St. John's lawyer, to bring forward a class action suit against Eastern Health.
- 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 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 provided a briefing to the HCS Minister on November 23. The details are as follows:

-	Total Cases Reviewed 1997-2005	2760
-	Total Patients Retested	939
-	Results Obtained and Reviewed	939
-	Patients Who Are Deceased	176
-	Patients	117

Further details on the retesting results are attached.
- 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.
- CBC News reported on November 23 on the problems with ER/PR testing, the length of time (18 Months) the review is taking and lack of public communication on the matter.

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ER/PR CASE ANALYSIS**Eastern
Health****BRIEFING FOR THE DEPARTMENT OF
HEALTH AND COMMUNITY SERVICES: NOVEMBER 23, 2006**

Total cases reviewed 1997-August 2005: 2760 cases

Total retested: 939.

Results obtained and reviewed: 763

- ✓ No change in results and subsequently no change in treatment: 433
 - Confirmed negative: 341
 - Confirmed negative from panel: 28
 - Confirmed positive: 12
 - DCIS: 52
- ✓ No change in results; requires change in treatment as definition of negative has changed: 13
- ✓ Change in results but does not require treatment change: 213
 - No recommendation because they are low risk: 60
 - No recommendation because they are previously treated with Tamoxifen or another aromatase inhibitor: 148
(This group includes a group identified as being potentially impacted: those not placed on Tamoxifen for their original disease, but for subsequent metastatic disease (13))
 - No treatment because they required assessment prior to recommendation: 5
- ✓ Change in results and requires treatment change: 104
 - Recommended for treatment with Tamoxifen or aromatase inhibitor: 96
 - Originally diagnosis revised: 4
 - Originally had a degree of ER positivity but on retesting was negative: 4

Patients who are deceased (176):

- ✓ 101 were retested and results received
- ✓ There have been 2 retested upon request. The remaining 73 will not be retested unless the families approach us.