

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 but they are still not saying what went wrong or how many women got false results.

Anticipated Questions:

- Why is it taking so long for cancer survivors to get answers?
- Have all those affected been notified of their test results?
- Are all test results back from Mount Sinai?
- What assurances can you give the public that this won't happen again?

Key Messages:

- Our first priority was and continues to be the patients who had negative ER/PR results. I would like to assure the public that we take these matters seriously and there is a team of clinical and administrative people working on this issue. We are dedicated to improving the system, learning from our experiences and ensuring quality care.
- More than 900 test samples were sent to Mount Sinai Laboratory and all the test results are back. Eastern Health has made every effort to contact the patients or families involved. This review is in the final stages and should be concluded in the near future. Eastern will provide a briefing to the public within a week or two.
- Eastern Health has put a number of measures in place to reduce the risk of a recurrence of a similar issue. Eastern Health expects to begin testing of new patients in St. John's shortly after the review is completed.
- While this has been an unfortunate event for all of us, we are focused on ensuring patients have every treatment option that may be available to them and on addressing system issues that arise.

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.
- Eastern has not publicly released the results of the retesting at this time except confidentially to individual patients. The Authority is currently reviewing all charts to ensure that all individuals have been contacted. The full review should be completed by the end of November or early December.
- 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	763
- Patients Who Are Deceased	176

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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