

Questions and Answers Briefing Note Department of Health and Community Services

Title: Retesting of Breast Cancer Patients

Issue: Breast cancer patients are struggling for answers these days. Some patients may have missed out on a drug therapy (Tamoxifen) that lowers the risk of the cancer recurring. Some patients say it is hard to find out whether their results are right or not.

Anticipated Questions:

- When did the HCS Minister find out about the inaccurate cancer test results?
- How did this happen? What is being done to correct this problem?
- Can the HCS Minister assure the public that our health system is safe?
- Why did it take so long to let cancer patients know about the inaccurate test results? Have all patients been notified?

Key Messages:

- Health care is a priority for this Government and patient safety is first and foremost. Eastern Health has discovered a problem with the testing of tissue samples for breast cancer patients with ER/PR receptors and retesting is underway at Mount Sinai Hospital in Toronto.
- The problem was discovered in May and a quality review began immediately. Determining what happened with the testing of tissue samples is critical and a priority for Eastern Health and this Government. The situation is disturbing for all of us.
- Only a small percentage of breast cancer patients may be affected by the retesting as treatment for breast cancer is based on several factors, not just ER and PR.
- The process of contacting patients on the ER/PR situation is ongoing. Overall, the patient contacts have gone quite well.

Other Suggested Response(s):

- There are a number of steps in the testing process. Any problem in any step can cause a problem with the test results. When the problem is identified, changes in policies and practices may be necessary to minimize any recurrence of inconsistent test results.
- Until the quality review is completed, the testing of new breast cancer patients with ER/PR receptors is being done at Mount Sinai. Eastern Health is working to resolve this problem as quickly as possible.
- Patient safety is a primary focus for our health system. Regional health authorities have embarked on a national Safer Health Care Now campaign to implement six targeted interventions in patient care, e.g. rapid response teams, prevention of adverse drug events, improved care for heart attack patients.
- Patient safety is a national focus. FPT Health Ministers have set up a Canadian Patient Safety Institute to develop a national strategy for improving patient safety

in Canada. The Institute is designed to promote innovative solutions, and to facilitate collaboration amongst governments and stakeholders to enhance patient safety.

Background:

- In May, the laboratory at the Health Sciences Centre discovered some 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.
- Eastern Health is sending previously collected tissue samples for patients who had negative ER and PR results from 1997 to 2005 to Mount Sinai for retesting. Patients are not required to come to the hospital or have any additional testing.
- About 350 breast cancer tests are done annually in this province. About 73% of all cancer patients tested positive for ER and PR. These patients are not impacted by the retesting. The retesting involves about 27% of all patients.
- The retesting involves 611 patients, of whom 158 patients are deceased. The remaining 453 patients include 147 whose retesting has been reported by Mount Sinai, 285 patients whose test results have not been received and 21 patients in nursing homes/St. Pierre.
- The test results on the 147 patients reported by Mount Sinai include 88 patients that are confirmed negative and 59 patients under review by a panel consisting of two medical oncologists, two pathologists, two surgeons and a quality enhancement professional.
- A quality review started in May. It has included an internal review of testing processes, and an external review by the Chief Pathologist at the BC Cancer Institute and the Chief Technologist at Mount Sinai Hospital.
- The laboratory problem at the Health Sciences Centre could be repeated across Canada. An expert in medical technology has publicly stated that Canada lacks a national standards body and labs across the country should take a look at what they are doing to make sure they get it right.
- Eastern Health has advised the public that information on the ER/PR retesting can be obtained by calling the Patient Relations Officer at 777-6500, or their surgeon, oncologist or family doctor.
- There have been a lot of stories in the media on this issue. Recent headlines include: The Independent, October 2 – Questionable Results, The Telegram, October 5 – Breast Cancer Testing Suspended, and The Globe and Mail, October 6 – Flawed Test Imperils Scores of Cancer Patients.
- Eastern Health (Dr. R. Williams, V.P.- Quality, Diagnostic and Medical Services) has done a number of interviews. Peter Dawe, Canadian Cancer Society, spoke very strongly on this issue saying, “There is absolutely no doubt that there is a group of women out there that didn’t get proper treatment and that could have very dire consequences.”

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