From: Marilyn McCormack
To: Moira Hennessey
Date: 8/18/2006 10:59:24 AM
Subject: BN for Premier on ER/PR Receptor Tests

Hi Moira

Attached is the **FINAL** copy of the above noted Briefing Note if you approve of same. I had to go back to Heather to ask how many women were most impacted by the change in status of the ER/PR receptor testing. She gave me the number 22 as indicated on the third page of the BN. Gary also wanted to know how many were likely to initiate legal action and according to Heather any or all of the 939 women(or their families) could do so. Eaxact numbers would not be known at this time. She explained that even if the results were correct from the initial testing to the retesting at Mount Sinai the stress caused to some women/families by knowing they were being retested , how long they had to wait for information, etc. could be a basis to inititate an action or to participate in the class action if thats the way this proceeds..

If ydu are okay with this note Gary has approved it and it will go as is. Please advise as soon as possible

Marilyn

Briefing Note

Title: Update on Pathology Reports and Legal Action for Women Diagnosed with Breast Cancer

Issue: Current status of pathology testing and legal claims related to women diagnosed with breast cancer.

Background:

- In May, 2005 the laboratory at the Health Sciences Center discovered some inconsistent results in breast tumor samples. Specifically ER (estrogen) and PR (progesterone) receptor tests which were completed to determine whether a particular tumor needed hormones, such as estrogen or progesterone to grow, varied in a number of samples.
- The result of receptor tests direct the treatment to be provided. For example, women who had a positive test result from the receptor test may respond to hormone therapy such as the drug Tamoxifen. Tamoxifen is taken by mouth and generally carries fewer side effects than other forms of treatment for cancer such as chemotherapy. If ER and PR tests are negative the patient is given chemotherapy.
- Since the discovery of these inconsistent results Eastern Health has sent 939 collected tissue samples for patients who had tested negative ER and PR results from 1997-2005 to Mount Sinai for retesting. Test results have been received on 923 patients.
- Eastern Health also established a panel of professionals representing medical oncology, pathology, surgery, and quality services (NL Panel) who reviewed the test results coming back from Mount Sinai whenever there was a change in the patients initial test results.

Current Status: (Pathology Reports)

The total number of patient tissues sent for retesting at Mount Sinai was 939 and the majority of the test results (923) have been returned. The following table details the results from Mount Sinai and also provides information on the 422 test results with changes that were reviewed by the NL panel upon receipt from Mount Sinai.

The test results include:

Category	Number	Comments
Patient test results confirmed negative by Mount Sinai	341	No change in patient's treatment plan.
Patient test results confirmed negative by NL panel	28	Patients whose original test results were considered negative by treating physician and treated appropriately. There was a slight change in ER/PR status as a result of the testing at Mount Sinai but following a second review by the NL panel the negative

		ER/PR status was confirmed.
Patient test results confirmed positive by NL panel	12	Patients whose original test results were considered positive by treating physician and treated appropriately. There was a slight change in ER/PR status but review by NL panel confirmed positive ER/PR status.
Patient ER/PR status changed from negative to positive but no treatment recommendations	208	There are 13 patients of the 208 who are being treated for metastatic disease. However these patients began treatment since their original diagnosis but before the test results were reviewed by Mount Sinai and the NL panel therefore there are no treatment recommendations for them. The remainder Includes patients deemed at low risk of recurrence, previously could not tolerate or did not want Tamoxifen, or have since been placed on Tamoxifen for metastic disease.
Patient ER/PR status changed from negative to positive and there are treatment recommendations	109	Includes patients who have been impacted by the delay in receiving Tamoxifen and patients whose results have not changed significantly but the clinical definition of positive and negative has changed since time of diagnosis.
Ductal Carcinoma in Situ (DCIS)	56	Tamoxifen is not recommended for DCIS. There are 39 confirmed and 14 under review. The panel has identified 3 patients who were incorrectly diagnosed in their original pathology report which may have led them to being treated excessively. One of these three women was diagnosed with invasive carcinoma when the review by the NL panel indicated it was DCIS. The other two women were diagnosed with DCIS with a large amount of invasive component but upon review, the invasive component is much less. Patients have been notified.
Required assessment prior to recommendation	5	Panel could not make a recommendation without seeing the patient. Information has been communicated to patient and follow-up care offered.
Retro converters	4	Patients considered positive at time of initial ER/PR testing. These individuals received hormonal treatment. Retesting at Mount Sinai confirmed

		these were false positives.
Patients identified as deceased by chart review or contact with family member	176	Based on June 2006 ethics review, a public statement will be made at the end of the ER/PR review that if family members want the results, they can contact Eastern Health.
TOTAL	**939**	

Current Status: (Legal Activity):

- Currently only **two** legal claims have been filed as follows:

  Michelle Hanlon. A claim was served on Eastern Health on behalf of Ms Hanlon in December, 2005. Ms Hanlon has subsequently passed away but her claim is being followed by her family. Ms Hanlon had originally tested ER/PR negative and therefore was not treated with Tamoxifen. Later she tested ER/PR positive. Eastern Health's defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

  Verna Doucette: This statement of claim was recently filed with the intention to proceed under the class action legislation. (This will be the model case). Ms Doucette also tested ER/PR negative and was not treated with Tamoxifen. Later she tested ER/PR positive. The next step in the process is for the Plaintiff's lawyer to file, with the court, the parameters in which he intends to proceed. This is part of the process in his application to the court to seek a class of patients to be certified.

  **Recent media reports identified Myrtle Lewis has joined other women who have signed on to take part in a class action lawsuit. Myrtle Lewis was completely misdiagnosed and as a result of an individual pathologist who read her test results wrong she has undergone radical surgery and extensive chemotherapy. Mrs. Lewis had pre-cancerous cells which did not require the extensive treatment she went through. The statement of claim filed by Mr. Ches Crosbie was served to the defendant, Eastern Health on July 7, 2006.

Summary:

The legal action initiated by Mrs. Myrtle Lewis is a result of a misdiagnosis and is not linked to the problems described in this note with the ER/PR receptor tests which had to be repeated.

Eastern Health advises 22 women were greatly impacted by the change in status of the ER/PR Receptor tests. These women had changes in the progress of their disease from the initial confirmation of the disease and the beginning of their treatment to the retesting done at Mount Sinai

However, all of the 939 patients (or families of those who have died) whose test results were reviewed **could potentially** become applicants in a class action lawsuit. The basis of their claims may differ depending on the criteria established. The lawyer initiating the suite has included in his claim for damages not only the problem with the lab where test results were inaccurate but also the stress suffered by those who were told in advance the testing was being repeated and the time they were required to wait before information was available to them on their individual cases. Currently legal counsel for Eastern Health is reviewing the legal position for Eastern Health.

Impacts of Treatment with Tamoxifen:

The drug Tamoxifen is believed to prevent the growth of cancer in ER/PR positive patients. It does have possible side effects which includes; endometrial cancer, blood clots in the legs, stroke, abnormal growth of uterine tissue, hair and nail thinning, and fertility problems. Patients however who do not receive Tamoxifen but are ER/PR positive may experience further problems with cancer.

Reasons for the Erroneous Results and Steps taken to Prevent Reoccurrence:

Eastern Health has engaged external consultants to review the procedures at the laboratory. When all reports are received they will be reviewed and the recommendations will be implemented. The goal is to have the laboratory accredited.

Until these processes are completed all samples will continue to be retested at Mount Sinai.

Action Required:

- This note is provided for information purposes only. Should the Premier require further detail officials from Eastern Health as well as their legal counsel will be available for an in person briefing.

Prepared by/Approved by: Heather Predham, Eastern Health; Moira Hennessey, HCS
Reviewed by: Marilyn McCormack; Gary Cake, Cabinet Secretariat
Date: August 18, 2006