

From: Tansy Mundon
To: Cake, Gary
Date: 7/31/2006 4:40:26 PM
Subject: BN - ER/PR

Gary,
As per John's request, please see attached briefing note prepared by Eastern Health regarding ER/PR.

Tks,
Tansy

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CC: Abbott, John

Prepared by: **Heather Predham,**
Assistant Director, Quality and Risk Management

Date: **July 31, 2006**

Re: **Estrogen and Progesterone Receptor Testing: Update**

The total number of patients sent for retesting was 939. The majority of results have been returned, reviewed and the individual patients informed. **Exceptions** to this are listed below:

Ductal Carcinoma In Situ (DCIS):

DCIS is a diagnosis made by the pathologist when the cancer cells grow inside the ducts of the breast. DCIS means that there is no, or only a very limited amount of, invasive component of the disease and this diagnosis would form the basis of the plan of treatment. As I understand it, from our specialists, Tamoxifen is not recommended for DCIS. There is, therefore, no reason to test the ER/PR status.

Of the results returned from Mount Sinai, there were ones that Mount Sinai did not retest as they diagnosed them as being DCIS. Initially, the panel reviewed the original pathology report and if that report diagnosed the person as having DCIS, then there was no further action required: the patient is confirmed DCIS and does not have to be retested for ER/PR.

If the panel could not do this initial step, then two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS".

However, our review has also revealed patients who were incorrectly diagnosed in their original pathology report with an invasive disease. This may have led them to being treated with Tamoxifen or chemotherapy. At this time, there are three women who fall in this category. Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care have disclosed this information to those affected.

There are **14** more DCIS patients throughout Newfoundland and Labrador that require further review by pathology.

"Retro" Convertors

All patients who were negative for ER were included in the retesting process. As the clinical definition of negative changed over the years, all patients with an ER of 30% or less were retested.

That means that in the group retested there are women who, although their ER level met this definition of negative, were considered positive at the time and received hormonal treatment. However, in **4** cases, retesting by Mount Sinai identified that women in this category now have an ER/PR status of 0% which has been confirmed by subsequent retesting at Mount Sinai.

Representatives of Eastern Health and the Clinical Chiefs of Pathology and Cancer Care will meet with them in the near future to disclose this information.

Deceased

174 patients are identified as being deceased. In June, an ethics review was conducted regarding notification of these families. The recommendation was that upon conclusion of the ER/PR review, a public statement be made stating that if the next of kin of a deceased patient would like the results, that they contact Eastern Health.

Legal activity

Hanlon claim

This claim was served on Eastern Health in December 2005. Ms. Hanlon has subsequently passed away. Eastern Health's defense has been filed and currently a list of pertinent documents is being prepared for submission to the court.

Doucette Claim

This statement of claim was recently filed with the intention to proceed under the class action legislation. The next step in this 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.