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From: Heather Predham

To: George Tilley;

Subject: Briefing Note

Date: July-05-06 4:59:37 PM Attachments: Briefing Note July 4.doc

Hi,

Dr. Williams asked me to do this up for you.

As we were meeting in the am about the OCR, and you might have a question or two, I thought I would get this over to you.....

Heather.

To: Dr. R. Williams, V.P., Quality, Diagnostic and Medical Services

Mr. George Tilley, President and CEO

Ms. Pat Pilgrim, C.O.O., Cancer, Child and Women's Health, Rehabilitation

Ms. Pam Elliot, Director, Quality and Risk Management

From: Heather Predham, Assistant Director, Quality and Risk Management

Date: July 4, 2006

Re: Estrogen and Progesterone Receptor Testing: DCIS and Retro Convertors

I need to bring your attention to two situations that have developed during our ER/PR review:

## 1. 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, DCIS tumors do not respond to Tamoxifen in the way invasive cells do. 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. 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 level of review, then two pathologists reviewed the original blocks and slides. This has led to the identification of other "confirmed DCIS".

However, this 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 will meet with them in the next few weeks to disclose this information.

We are waiting for four more patients to be reviewed by the pathologists and five more that have been reviewed require further discussion at the panel to determine follow-up.

The Medical Directors in Central and Western Boards will be contacted to see if they wish to review their patients identified as DCIS within their own board or if they would prefer Eastern Health to do their patients.

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## 2. 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 four 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 next few weeks to disclose this information.

I will update you as we deal with the remaining patients in the DCIS category. If you have any questions, please do not hesitate to contact me.